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No.

In the Supreme Court of the United States

October Term, 1986

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F.
BAUER, JOHN D. BURROWS, RUSSELL C. HUMPHREY,
JR., SIMON E. MILLER, IBA, INC., DANIEL BELSITO,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

PETITION FOR WRIT OF CERTIORARI To the United States Court of Appeals For the Sixth Circuit

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QUESTIONS PRESENTED

The Sixth Circuit issued an opinion below which precludes defendants, charged with misbranding of an animal drug, from asserting the statutory defense of adequate directions for use specifically set forth in §502(f) of the Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. §352(f).

The decision further estops distributors of animal drugs used by dairy farmers from defending such actions because of administrative concessions by third parties in prior proceedings to which the distributors were not and could not be parties. The questions which arise are:

1. Can, consistent with due process, a trial court collaterally estop drug distributors from defending an FDA enforcement action because third parties made concessions in a prior administrative proceeding to which the distributors were not and could not be parties?

2. Did the trial and reviewing courts erroneously "defer" to agency interpretations of the FDCA which ignore both the plain language and Congressional intent of the statute by declaring that: (1) animal drugs' manufacturers' voluntary concessions restricting the resale of certain animal drugs establishes, as a matter of law, that the directions accompanying the drugs are inadequate for lay use; and (2) that "prescription or other order of a licensed veterinarian" cannot encompass an oral order from a veterinarian to an animal's owner?

LIST OF PARTIES AND RULE 28.1 STATEMENT

The Petitioners IBA, Inc., a Massachusetts corporation, and Daniel J. Belsito, President of IBA, are wholesalers of veterinary drugs who sell to independent distributors and dealers located across the United States. Neither IBA nor Belsito sell any veterinary drugs to end users, and, for purposes of the decision below, were "regularly and lawfully engaged in the distribution of drugs." App. at A43. Jerry Colahan is an IBA distributor in Ohio, and the other Petitioners are dealers and route salesmen who retail the drugs to dairy farmers and other farmers. The United States Attorney instituted this action on behalf of the Food & Drug Administration pursuant to 21 U.S.C. §332, which authorizes injunctive relief for violations of the FDCA.

IBA, Inc. has one subsidiary, Plymouth Manufacturing Company. It has no parent or other affiliated company.

III

TABLE OF CONTENTS

| | |
|---|-----|
| QUESTIONS PRESENTED | I |
| LIST OF PARTIES AND RULE 28.1 STATEMENT | II |
| TABLE OF CONTENTS | III |
| TABLE OF AUTHORITIES | V |
| OPINIONS BELOW | 1 |
| JURISDICTION | 2 |
| STATUTES AND REGULATIONS INVOLVED | 2 |
| STATEMENT OF THE CASE | 3 |
| A. Background | 3 |
| B. FDA's Claims Against Petitioners | 5 |
| C. Procedural History | 6 |
| D. The Sixth Circuit Opinion | 8 |
| REASONS FOR GRANTING THE WRIT | 11 |
| I. THERE IS A CLEAR CONFLICT WITH PRINCIPLES OF COLLATERAL ESTOPPEL AND DUE PROCESS ENUNCIATED BY THIS COURT | 11 |
| II. THE DECISION IS IN CONFLICT WITH OTHER CIRCUITS | 16 |
| III. THE DECISION BELOW WILL HAVE CON- TINUING IMPACT ON THE ONGOING LIT- IGATION AGAINST THE ANIMAL DRUG INDUSTRY | 18 |
| CONCLUSION | 20 |

IV

APPENDIX (under separate cover):

| | |
|--|-----|
| Opinion of the United States Court of Appeals for the Sixth Circuit (February 5, 1987) | A1 |
| Post-Judgment Memorandum Opinion and Order of District Court (June 24, 1985) | A24 |
| Judgment Entry of District Court (May 25, 1985) | A29 |
| Memorandum Opinion and Order of District Court (May 25, 1985) | A31 |
| Opinion of the United States Court of Appeals for the Sixth Circuit (December 11, 1980) | A49 |
| Memorandum Opinion and Order of District Court (October 9, 1979) | A58 |
| 21 U.S.C. §321(w) | A67 |
| 21 U.S.C. §331(a-d) | A68 |
| 21 U.S.C. §332(a-b) | A68 |
| 21 U.S.C. §352(f) | A69 |
| 21 U.S.C. §360b | A70 |
| 21 C.F.R. §201.105 (1986) | A77 |

TABLE OF AUTHORITIES

Cases:

| | |
|--|---------------|
| <i>Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation</i> , 402 U.S. 313 (1971) | 11 |
| <i>Chevron USA, Inc. v. Natural Resources Defense Council, Inc.</i> , 467 U.S. 837 (1984) | 14 |
| <i>CIBA Corp. v. Weinberger</i> , 412 U.S. 640 (1973) | 12, 13, 16 |
| <i>Ewing v. Mytinger & Casselberry</i> , 339 U.S. 594 (1950) | 12 |
| <i>Parklane Hosiery Co., Inc. v. Shore</i> , 439 U.S. 320 (1979) | 12 |
| <i>Premo Pharmaceutical Laboratories, Inc. v. United States</i> , 629 F.2d 795 (2d Cir. 1980) | 17 |
| <i>Security Industry Assn. v. Board of Governors</i> , 468 U.S. 137 (1984) | 14 |
| <i>United States v. Article of Drugs, . . . Lannett</i> , 585 F.2d 575 (3d Cir. 1978) | 16 |
| <i>United States v. Article of Device . . . Toftness</i> , 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) | 17 |
| <i>United States v. Colahan</i> , 811 F.2d 287 (6th Cir. 1987) | <i>passim</i> |
| <i>United States v. Colahan</i> , 635 F.2d 564 (6th Cir. 1980) | 2 |
| <i>United States v. Colahan, Slip Op.</i> , Case Nos. C78-1470, C80-472A (N.D. Ohio, May 25, 1985) | 2, 4, 6 |
| <i>United States v. Colahan, Slip Op.</i> , Case No. C78-1470A (N.D. Ohio, October 9, 1979) | 2 |
| <i>United States v. Generix Drug Corp.</i> , 460 U.S. 453 (1983) | 17 |

VI

| | |
|--|----|
| <i>United States v. Utah Construction & Mining Co.</i> , 384 U.S. 394 (1966) | 12 |
| <i>United States v. X-OTAG Plus Tablets</i> , 602 F.2d 1387 (10th Cir. 1979) | 17 |

Statutes and Regulations:

| | |
|---|-------------------|
| Federal Food, Drug & Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. §§321-360 | |
| Section 201, 21 U.S.C. §321(w) | 2, 5 |
| Section 301, 21 U.S.C. §331(a-d) | 2 |
| Section 302, 21 U.S.C. §332(a-b) | 2 |
| Section 502(f), 21 U.S.C. §352(f) | 2, 3, 10 |
| Section 503(b), 21 U.S.C. §353 | 10 |
| Section 512, 21 U.S.C. §360b | 2, 5 |
| 21 C.F.R. §201.105 | 2, 4, 6, 7, 9, 10 |

Miscellaneous:

| | |
|---|----|
| Bureau of Veterinary Medicine, HEW Pub. No. (FDA) 74-6012, Revd. May, 1978 | 15 |
| FDA Compliance Policy Guide No. 7125.03, October 1, 1980 | 14 |
| Kushen, <i>FDA: A Case Study in Administrative "Legislation,"</i> 24 THE BUSINESS LAWYER 261 (1968) | 14 |

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Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

**PETITION FOR WRIT OF CERTIORARI
To the United States Court of Appeals
For the Sixth Circuit**

The Petitioners, Jerry J. Colahan, d/b/a IBA of Ohio, Norman F. Bauer, John D. Burrows, Russell C. Humphrey, Jr., Simon E. Miller, IBA, Inc., and Daniel Belsito, respectfully ask that a Writ of Certiorari issue to review the judgment and opinion of the United States Court of Appeals for the Sixth Circuit entered in this proceeding on February 5, 1987.

OPINIONS BELOW

The opinion of the Court of Appeals in *United States v. Colahan* is reported at 811 F.2d 287 and is reprinted in the Appendix ("App.") at A1. The opinion and order of

the District Court granting summary judgment is unprinted and appears at App. at A31. A prior Sixth Circuit opinion in this case was published at 635 F.2d 564 and is reprinted, App. at A49. The unpublished opinion of the District Court leading to the first appeal appears at App. at A58. This Court denied certiorari of the prior Sixth Circuit decision, 454 U.S. 831 (1981).

JURISDICTION

The decision of the Court of Appeals was entered on February 5, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1) and 28 U.S.C. §2101(C).

Jurisdiction was conferred on the Court of Appeals by the filing of a timely Notice of Appeal.

STATUTES AND REGULATIONS INVOLVED

The following statutes and regulations are reprinted in the Appendix:

1. Section 201 of the Food, Drug & Cosmetic Act, 21 U.S.C. §321(w) (App. A67).
2. Section 301 of the Food, Drug & Cosmetic Act, 21 U.S.C. §331(a-d) (App. A68).
3. Section 302 of the Food, Drug & Cosmetic Act, 21 U.S.C. §332(a-b) (App. A68).
4. Section 502(f) of the Food, Drug & Cosmetic Act, 21 U.S.C. §352(f) (App. A69).
5. Section 512 of the Food, Drug & Cosmetic Act, 21 U.S.C. §360b (App. A70).
6. 21 C.F.R. §201.105 (1986) (App. A77).

STATEMENT OF THE CASE

A. Background

Dairy farming is an industry which requires constant care to its primary resource, cattle. Such care includes administering veterinary drugs such as vitamin supplements, prophylactic medication, and salves and injections for irritations and illnesses. Many of these drugs are available in feed stores and supply stores and are routinely administered by the farmers.

Animal drugs, as human drugs, are under the general jurisdiction of the FDA to insure that: (1) drugs which are not both safe and effective are not marketed; and (2) adulterated or misbranded drugs are not sold.

In 1978, the FDA brought suit against Petitioners Jerry Colahan, and others, claiming that they received and sold various animal drugs that were misbranded under Section 502(f) of the FDCA, 21 U.S.C. §352(f)(1). Section 352(f)(1) deems a drug to be "misbranded," unless its labeling bears "adequate directions for use."¹

That same section allows the agency to promulgate regulations exempting animal drugs from the "adequate directions" requirement where such directions are "not

1. The statute provides:

A drug or device shall be deemed to be misbranded—

(f) Unless its labeling bears (1) adequate directions for use . . . *Provided*, that where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

App. at A69.

necessary for the public health." Pursuant to this authority, the FDA promulgated 21 C.F.R. §201.105, exempting a veterinary drug:

. . . which, because of toxicity or other potentiality for harmful effect, or the method of its use is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared

App. at A77. Those drugs are not misbranded if they bear a label reading:

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

App. at A77, and are in the possession of a person:

. . . regularly and lawfully engaged in the . . . wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice.

Id.

The government made similar allegations in a suit filed in 1979 against Petitioners IBA, Inc. and Belsito in Massachusetts. IBA, Inc., however does not sell animal drugs retail. It sells only to independent dealers and distributors.²

The *IBA, Inc.* case was consolidated with the *Ohio Colahan* case.

2. The Trial Court, for purposes of its decision, agreed that Petitioners were "regularly and lawfully engaged in the distribution of drugs." App. at A43.

B. FDA's Claims Against Petitioners.

Of the 17 animal drugs alleged to be misbranded, 15 were classified by the FDA as "new animal drugs" (NADs).³ The FDA approved the interstate marketing of these drugs by accepting the NADAs submitted by the drugs' manufacturers. As part of the NADAs, the manufacturers stated they would place a restrictive label on the drugs:

Caution: Federal law restricts this drug to sale by or on order of a licensed veterinarian.

In so doing, the manufacturers were able to receive approval whether or not the drugs were toxic or the directions accompanying the drug were adequate for lay (i.e. dairy farmers') use on cattle. The adequacy of the directions was not an administrative issue where the manufacturer agreed to use the "cautionary" labels.

If the Secretary approved the application within 180 days, neither notice nor a hearing was necessary and the NADA became effective without any opportunity for a party who would be affected by the restrictive labelling to participate. 21 U.S.C. §360b(c). App. at A72-73.

The government claims that 17 drugs sold by Petitioners were "misbranded."⁴

3. A "new animal drug" is:

... any drug intended for use for animals other than man
... that ... is not generally recognized, among experts
... as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ...

21 U.S.C. §321(w), App. at A67.

4. Also at issue was whether IBA, Inc., which did not sell any veterinary drugs to end users, could be charged with misbranding on the sole grounds that it was the source of the drugs' overall marketing system. No evidence was offered to show that IBA, Inc. did or could "police" the resale of its veterinary drugs to farmers.

Two of the animal drugs were not subject to a pending NADA. The government claimed they were "misbranded," because they also had the cautionary label (though not required by any pending NADA) and were sold directly to farmers.

C. Procedural History.

The District Court issued an opinion in the *Colahan* case that, the FDA had no statutory authority to promulgate 21 C.F.R. §201.105, which allegedly establishes a "prescription" category for some animal drugs (App. at A58), enjoined the United States from further prosecution of the *IBA, Inc.* case on those grounds, and ordered transfer and consolidation of the *IBA, Inc.* case with the *Colahan* case. The Sixth Circuit reversed the Trial Court decision which invalidated §201.105 and remanded for further proceedings.

This Court denied certiorari. In their brief opposing certiorari, the United States acknowledged that the adequacy of the drugs' labels and directions was still to be litigated:

[T]he Court of Appeals has neither permanently enjoined their distribution of the nine disputed drugs nor has it prevented petitioners from demonstrating that these drugs can be adequately labeled for lay use. In fact, the court directed the lower court to conduct further proceedings.

Brief in Opposition to the Petition, etc. (Case No. 80-2067) p. 13, n.11.

After remand from the Sixth Circuit, the consolidated cases were assigned to a magistrate for resolution of pre-trial discovery disputes. The magistrate requested the

parties to brief four legal issues to narrow the scope of discovery. Instead the United States filed a Motion for Summary Judgment, now claiming that the presence of the "cautionary" label alone estopped Petitioners from proving that the drugs had adequate directions for lay use.

Petitioners opposed, filing a Brief and the Affidavit of Dr. William H. Lederer, a toxicologist who testified that he was in the process of analyzing each of the contested drugs and, so far, had concluded that the labeling of NAD dexamethasone was adequate for a lay person to use the drug in the treatment of animals. Prior to oral argument on the Motion for Summary Judgment, Petitioners learned that Dr. Lederer had died and filed a Motion for Leave to engage another expert.

The Motion for Leave was never ruled upon. The Court granted the government's Motion for Summary Judgment and entered an injunction which prohibited Petitioners from introducing 16 of the drugs into interstate commerce until they complied with 21 C.F.R. §201.105. In the absence of any evidence that Petitioners "misbranded" epinephrin, the Court sua sponte issued a declaratory order that sales of that drug in dosages exceeding 10 ml. would violate the misbranding statutes. In a post-judgment memorandum and order, the Court removed NAD nitrofurazone from the list of enjoined drugs "[u]pon stipulation by the government that this drug is presently permitted to be sold without a prescription" App. at A27-28. In other words, the government agreed that nitrofurazone was generally available OTC and thus not misbranded, even though it was classified as a new animal drug by the FDA and carried a cautionary label. The Court further clarified that in order to comply with 21 C.F.R. §201.105, there must be "direct communication . . .

oral or written . . . between a veterinarian and the dispenser of the drug." App. at A25. An oral order directly from the veterinarian to the animal's owner would not suffice. App. at A25. The Sixth Circuit affirmed.⁵

D. The Sixth Circuit Opinion.

The Sixth Circuit framed the issue as:

. . . whether FDA can reasonably determine that approval of an NAD with labeling restricting resale of the drugs only upon a licensed veterinarian's order, renders that NAD subject to 21 C.F.R. §201.105 and the misbranding provisions without requiring FDA to demonstrate the toxicity of the drugs in a misbranding action.

811 F.2d at 292. The Court concluded that the FDA had no such duty "when the manufacturer itself proposes a label that states the NAD is not to be used except upon the order of a licensed veterinarian," and further:

Defendants [Petitioners] should not be permitted to bypass FDA procedures and policies that seek to impose upon FDA the burden of proving a fact which was conceded in the original process by which FDA gave its approval to these NADs for the specific uses under defined conditions.

Id.

Although the Court referred to the "burden of proving a fact," burden of proof was not at issue. By affirming the summary judgment, the Circuit Court absolved the gov-

5. Despite the Trial Court's holding that the order may be "oral or written," the Sixth Circuit held that the drugs could be sold only by "express prescription or other written order of a veterinarian." 811 F.2d at 293, App. at A12-13.

ernment from *any* showing regarding the toxicity or harmfulness of the drug, while Petitioners were denied the opportunity to prove the safety—i.e. nontoxicity—of the drugs.

As promulgated, 21 C.F.R. §201.105 applies, only where an animal drug is unsafe because of its “toxicity or other potentiality for harmful effect.” The *Colahan* Court held that because these facts were “conceded” by the manufacturer, the government did not even have to show a *prima facie* case of toxicity, etc., and Petitioners were estopped from contesting the “conceded” facts.

The dissenting judge indicated that the issue to be considered should be:

Whether the findings necessarily made during the NAD approval process, and which resulted in a requirement that these drugs bear the cautionary label, collaterally establish the factual predicate of section 201.105 that the drug is unsafe for use without veterinary supervision.

Id. at 295. He concluded that “all that can be presumed from the NAD application approval is that the drug is safe with the cautionary label; *it does not follow that the label is necessary to make the drug safe.*” *Id.* at 296 (Emphasis supplied). Therefore, in the dissenter’s view, the District Court’s:

. . . ruling that the New Animal Drugs are covered by section 201.105 was based solely on the improper collateral use of the NAD application approval. *Thus, there was no showing that the drugs are in fact unsafe for use without veterinary supervision.* (Emphasis supplied.)

Id.

But further, the Court of Appeals completely ignored the question of whether animal drugs with adequate directions for lay use can *ever* be misbranded, regardless of the presence of a cautionary label. Section 352(f), the statutory authority for 21 C.F.R. §201.105⁶ provides that animal drugs are misbranded *unless* they have adequate directions for use. The government conceded that the drugs at issue contained adequate directions for use or, at the very least that Petitioners could prove adequate directions for use on remand from the Sixth Circuit. Petitioners were prepared to show that the drugs had such directions; the District Court precluded them from doing so; and the Court of Appeals ignored this basic issue.

6. The alleged statutory basis is, at best, tenuous. Whereas, Congress provided specific statutory authority for a prescription category of *human* drugs (§503(b), 21 U.S.C. §353), no such authority exists for animal drugs. The FDA must rely on the last sentence of 21 U.S.C. §352(f), which allows the FDA to promulgate regulations for animal drugs for which the misbranding prohibition "is not necessary for the protection of the public health."

REASONS FOR GRANTING THE WRIT

Under *Colahan*, any animal drug bearing the cautionary label is, as a matter of law, safe and effective only when distributed on the prescription or other order of a veterinarian. This is so even though the manufacturer may have volunteered to include the cautionary label to facilitate approval of the NADA. Further, by virtue of the presence of a cautionary label alone, adequate directions for lay use cannot be written for animal drugs distributed in the Sixth Circuit. This bootstrap argument contains no administrative factfinding at any point that the drug in question is potentially harmful if administered to cows by a dairy farmer or cannot contain adequate directions for lay use. Moreover, the Sixth Circuit rule binds parties who did not, and could not, participate in the FDA proceedings in which the NADA, with its labeling restrictions, was approved.

Finally, the Court gives undue deference to an overly narrow, irrational interpretation by the FDA of what is an order "of" a veterinarian.

I. THERE IS A CLEAR CONFLICT WITH PRINCIPLES OF COLLATERAL ESTOPPEL AND DUE PROCESS ENUNCIATED BY THIS COURT.

The Sixth Circuit held that Petitioners were estopped from challenging the necessity of the cautionary label by concessions made by the drugs' manufacturers in prior administrative proceedings. As this Court held in *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 329 (1971):

Some litigants—those who never appeared in a prior action—may not be collaterally estopped without liti-

gating the issue. They have never had a chance to present their evidence and arguments on the claim. Due process prohibits estopping them despite one or more existing adjudications of the identical issue which stand squarely against their position.

When, as in this case, the prior proceeding is administrative, due process requires not only that the party against whom it is sought to be applied participates, but that basic procedural guarantees are present:

When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it *which the parties have had an adequate opportunity to litigate*, the Courts have not hesitated to apply *res judicata* to enforce repose.

United States v. Utah Construction & Mining Co., 384 U.S. 394, 422 (1966) (Emphasis added). See also, *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 320 (1979) (in order to fulfill constitutional guarantees of due process and right to a jury trial, offensive use of collateral estoppel is limited to situations where the party against whom it is asserted had a full and fair opportunity to litigate the issue in a prior proceeding).

In *Ewing v. Mytinger & Casselberry*, 339 U.S. 594 (1950), this Court held that the FDA did not violate the due process clause of the Fifth Amendment when it exercised its discretion to determine that "probable cause" existed to institute multiple seizures of defendant's allegedly misbranded drugs, so long as the defendant "has an opportunity to appear as a claimant and to have a full hearing before the court." 339 U.S. at 598.

In *CIBA Corp. v. Weinberger*, 412 U.S. 640 (1973), this Court held that when a *manufacturer* participated in, and received judicial review of, the FDA's determination

that its drug was a "new drug," it could not relitigate the issue:

[P]etitioner, having an opportunity to litigate the "new drug" issue before FDA and to raise the issue on appeal to a court of appeals, may not relitigate the issue in another proceeding.

412 U.S. at 644. These cases compel the conclusion that defendants in an FDA enforcement proceeding must be given the right to challenge the FDA's characterization of the drug at issue unless the defendant can, and has, litigated the issue before the FDA with an opportunity for judicial review. At the very least, those characterizations cannot estop defendants where based on concessions by third parties without factfinding or judicial review.

In this case Petitioners never had the opportunity to contest or obtain judicial review of the FDA's conclusions that the challenged drugs were NADs that could be safely administered only under the supervision of a veterinarian. Under these circumstances, due process requires that Petitioners have the opportunity to prove that: (1) the challenged drugs are generally recognized as safe and effective and are therefore not NADs,⁷ and (2) adequate directions for lay use can, and have been written, so that the cautionary label is unnecessary. Petitioners were summarily denied that right under the Sixth Circuit decision and this Court should accept certiorari to conform Sixth Circuit law to these long-standing federal principles.

Even assuming that Petitioners were properly precluded from asserting that the cautionary labels were un-

7. For example, Petitioners should be permitted to demonstrate "bioequivalence" between the challenged drug and drugs presently available OTC, such as nitrofurazone.

necessary, the Sixth Circuit decision still obliterates the statutory intent of Congress that animal drugs shall be deemed to be misbranded only if they do not have adequate directions for lay use. The government has never alleged that the directions accompanying the 17 drugs were misleading, wrong, or inadequate for lay use. Their sole contention has been that although properly labeled, the drugs are misbranded by their method of sale. See, e.g., 811 F.2d at 289, App. at A4.

The court below cited *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) as requiring deference to the FDA interpretation that the presence of a cautionary label foreclosed Petitioners' proof that the drugs had adequate directions for use. This Court recognizes, however, that:

Judicial deference to an agency's interpretation of a statute "only sets the framework for judicial analysis; it does not displace it." . . . A reviewing court "must reject administrative constructions of [a] statute . . . that are inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement."

Security Industry Assn. v. Board of Governors, 468 U.S. 137, 143 (1984) (cites omitted).

Both legislative history⁸ and FDA's prior interpretations⁹ demonstrate that whether or not animal drugs

8. See, e.g., Kushen, *FDA: A Case Study in Administrative "Legislation,"* 24 THE BUSINESS LAWYER 261 (1968) (the legislative history of Durham-Humphrey Amendment "clearly supports" limiting prescription restrictions to drugs intended for use by man).

9. The FDA's own Compliance Policy Guide No. 7125.03, October 1, 1980, states:

The definition of "prescription drug" in the FDC Act does not apply to drugs for animal use, but the requirement that

(Continued on following page)

carry a cautionary label, they cannot be misbranded if they have adequate directions for lay use. As noted above, the government has even admitted in prior pleadings before this Court in this case that Petitioners should be permitted to show the drugs have adequate directions for use. This Court should accept jurisdiction to perform the judicial analysis never performed below and confirm that defendants in a misbranding suit cannot be foreclosed from showing that the drugs at issue contain adequate directions for lay use.

Finally, assuming that sales of the animal drugs in question are properly restricted, and the drugs do not contain adequate directions for use, the courts below gave undue deference to the FDA's interpretation of its own regulation that an "other order of a licensed veterinarian" must be direct between the veterinarian and the dealer. The demonstrated legislative and administrative intent to permit owners to diagnose and treat their own animal's illnesses "as they see fit" (see fn. 9) mandates an interpretation which allows the owner to obtain the restricted drug after confirming that he or she had received an oral order from a veterinarian for the drug.

Footnote continued—

the labelling of drugs bear adequate directions for use does apply to veterinary drugs. The interpreted view of Congress is that people have the right to treat their animals with any product for which reasonably adequate directions for safe use can be supplied in labeling.

See also, Bureau of Veterinary Medicine, HEW Pub. No. (FDA) 74-6012, Revd. May, 1978:

The Congress specifically omitted animal drugs from prescription legend requirements on the basis that a man's animals are his private property and he may diagnose and treat their ailments as he sees fit. This means that in any case where adequate directions for lay use may be written, the animal drug must be freely marketed

This Court should accept jurisdiction to enforce the "policy that Congress sought to implement."

II. THE DECISION IS IN CONFLICT WITH OTHER CIRCUITS.

The Sixth Circuit decision below conflicts with decisions of other circuits which recognize that defendants in misbranding actions can prevail by showing that the allegedly misbranded drugs have adequate directions for lay use or are generally recognized as safe and effective for their intended uses.

At least two circuits have interpreted *CIBA Corp., supra*, as a grant of concurrent jurisdiction between the FDA and district courts to determine the "new drug" status of a drug. Therefore, although the FDA may initially determine that a drug is a new drug, a defendant in a misbranding action brought by the FDA can challenge that status. Thus, in *United States v. Article of Drugs, . . . Lannett*, 585 F.2d 575 (3d Cir. 1978), the Third Circuit reversed summary judgment on a misbranding charge. The Trial Court held that the manufacturer was estopped from showing that the allegedly misbranded drug was not a new drug because it had not challenged the status before the FDA. Noting that the manufacturer had no prior opportunity to challenge the FDA determination and had no reason to write the FDA and request a change of classification until the misbranding action threatened its business, the Court of Appeals held: "The FDA and the District Court have given undue deference to the agency . . ." 585 F.2d at 581.

The Court held that on remand Lannett could challenge the new drug status by showing that the challenged drugs were "bioequivalents" of drugs sold OTC. Petitioners

had offered to make a similar showing, but were held to be precluded from doing so. See also, *Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795 (2d Cir. 1980) (the FDA and federal district courts have concurrent jurisdiction to determine new drug status in a declaratory judgment action). This Court approved *Premo* in *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983) (certiorari accepted and Court of Appeals reversed where "the question is obviously important and because it has been decided differently in other Circuits," 460 U.S. at 456, citing *Premo* as the conflicting case).

Other courts have assumed that in a misbranding action the burden is on the government to show that drugs are misbranded because they do not have adequate directions for lay use. *United States v. Article of Device . . . Toftness*, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) (where parties stipulated that where device was properly labeled as a prescriptive device, government met its burden of showing that it did not bear adequate directions for lay use); *United States v. X-Otag Plus Tablets*, 602 F.2d 1387 (10th Cir. 1979) (where parties agreed that if the challenged drugs did not meet the "new drug" status they were not misbranded, government sustained its burden of proving that the drugs did meet the "new drug" test).

The Sixth Circuit is, in fact, the only circuit which has stripped defendants of all defenses in injunction proceedings brought by the FDA. Interstate wholesalers, such as IBA, Inc., are therefore faced with conflicting standards in different areas of the country. This Court should grant certiorari to insure a uniform federal rule of animal drug distribution in the important agricultural industry of dairy farming.

III. THE DECISION BELOW WILL HAVE CONTINUING IMPACT ON ONGOING LITIGATION AGAINST THE ANIMAL DRUG INDUSTRY.

The United States' success in *Colahan* has led to the filing of similar suits. For example, in January of 1986, while the *Colahan* appeal was still pending in the Sixth Circuit, the Justice Department initiated an action against Southern Agriculture, Inc. of Tulsa, Oklahoma, and its president for misbranding veterinary drugs. Southern Agriculture, like some of the Petitioners, is a retail distributor of veterinary drugs with and without the cautionary labels and was accused of selling animal drugs bearing a cautionary label directly to farmers and ranchers.

If permitted to stand unchallenged, the *Colahan* decision will injure dairy farmers in the Sixth Circuit who depend upon comparably inexpensive, readily available animal drugs from wholesale and retail distributors and dealers. Farmers and ranchers, often isolated hundreds of miles from the nearest veterinarian, and responsible for hundreds of cattle, cannot practically or economically rely wholly on the services of veterinarians for the health of the animals. Under the rule of *Colahan*, a drug manufacturer's voluntary decision to avoid time and expense by offering to put a label on its drugs restricting its sale to the prescription or order of a veterinarian eliminates all flexibility and discretion for the farmer or the distributors of these drugs. A distributor haled into court for "misbranding" because drugs with the cautionary legend were sold directly to farmers are barred from proving that the animal drugs are generally recognized as safe and effective and/or are adequately labeled for lay use.

With the advent of *Colahan*, distributors in different parts of the country are subject to different legal standards.

Distributors and dealers in circuits that recognize a defendant's right to challenge the FDA's characterization of an animal drug as a "new animal drug" and/or the government's burden to show that directions are inadequate for lay use will be able to defend on those grounds. In marked contrast, distributors and dealers in the Sixth Circuit have lost that right. Ironically, in this case, the United States' own admission that one of the enjoined NADs was available OTC caused that drug to be removed from the injunction even though it had the cautionary label. A defendant in a misbranding action should not have to rely upon the largess of the government for its defenses, but should be permitted to a judicial determination based on evidence.

The United States has demonstrated its intention to sue distributors and dealers of veterinary drugs. This Court should insure that defendants in these actions have a full and fair judicial hearing.

CONCLUSION

Because the decision of the Sixth Circuit (1) is inconsistent with this Court's decisions on administrative collateral estoppel and due process, (2) gives undue deference to agency interpretations which conflict with the express language and legislative intent of the FDCA, and (3) conflicts with the rulings of other circuits, this Petition for Writ of Certiorari should be granted.

Respectfully submitted,

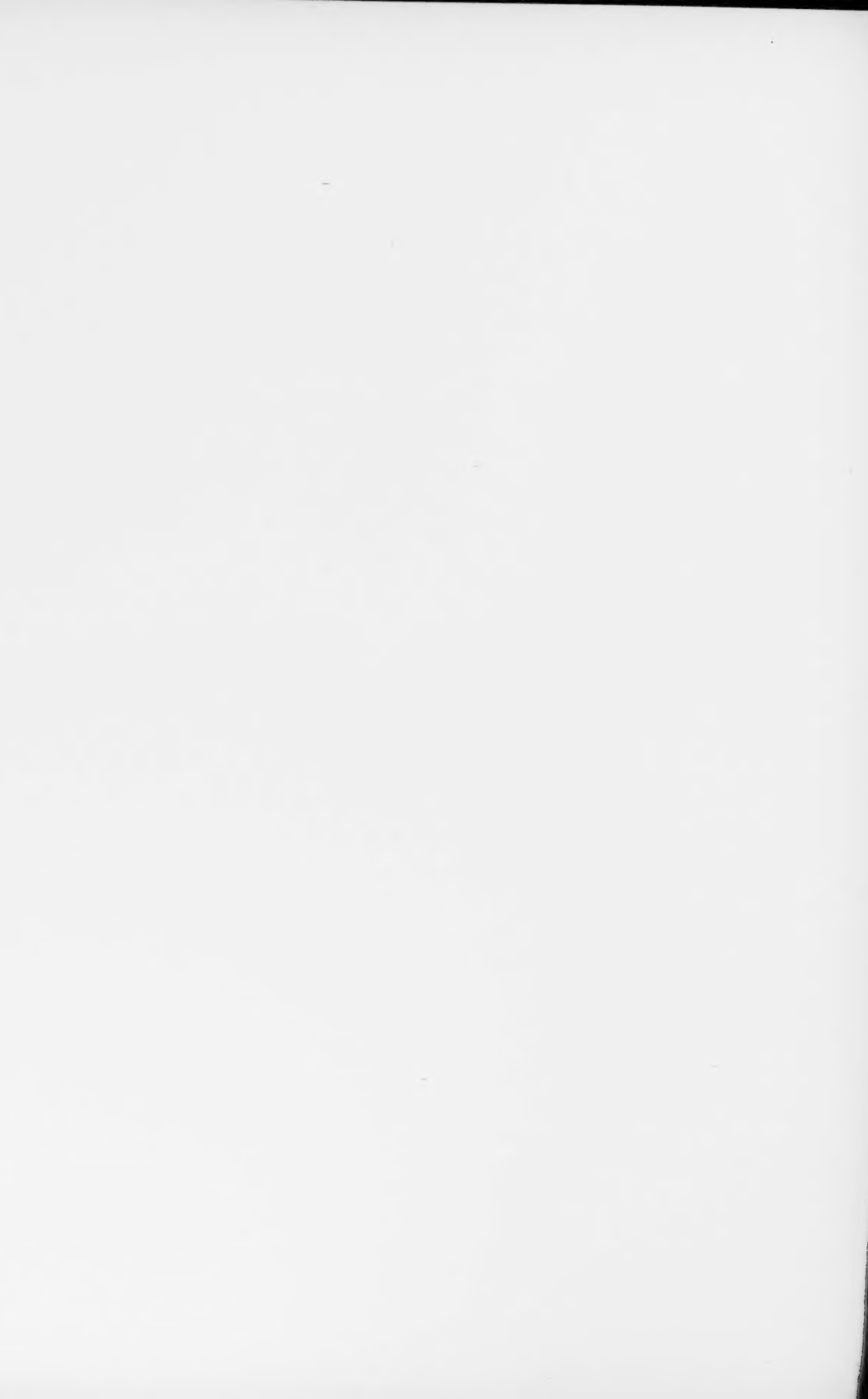
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Supreme Court, U.S.
FILED

MAY 6 1987

JOSEPH F. SPANIOL, JR.
CLERK

No.

In the Supreme Court of the United States

October Term, 1986

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F.
BAUER, JOHN D. BURROWS, RUSSELL C. HUMPHREY,
JR., SIMON E. MILLER, IBA, INC., DANIEL BELSITO,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

APPENDIX TO PETITION FOR WRIT OF CERTIORARI To the United States Court of Appeals For the Sixth Circuit

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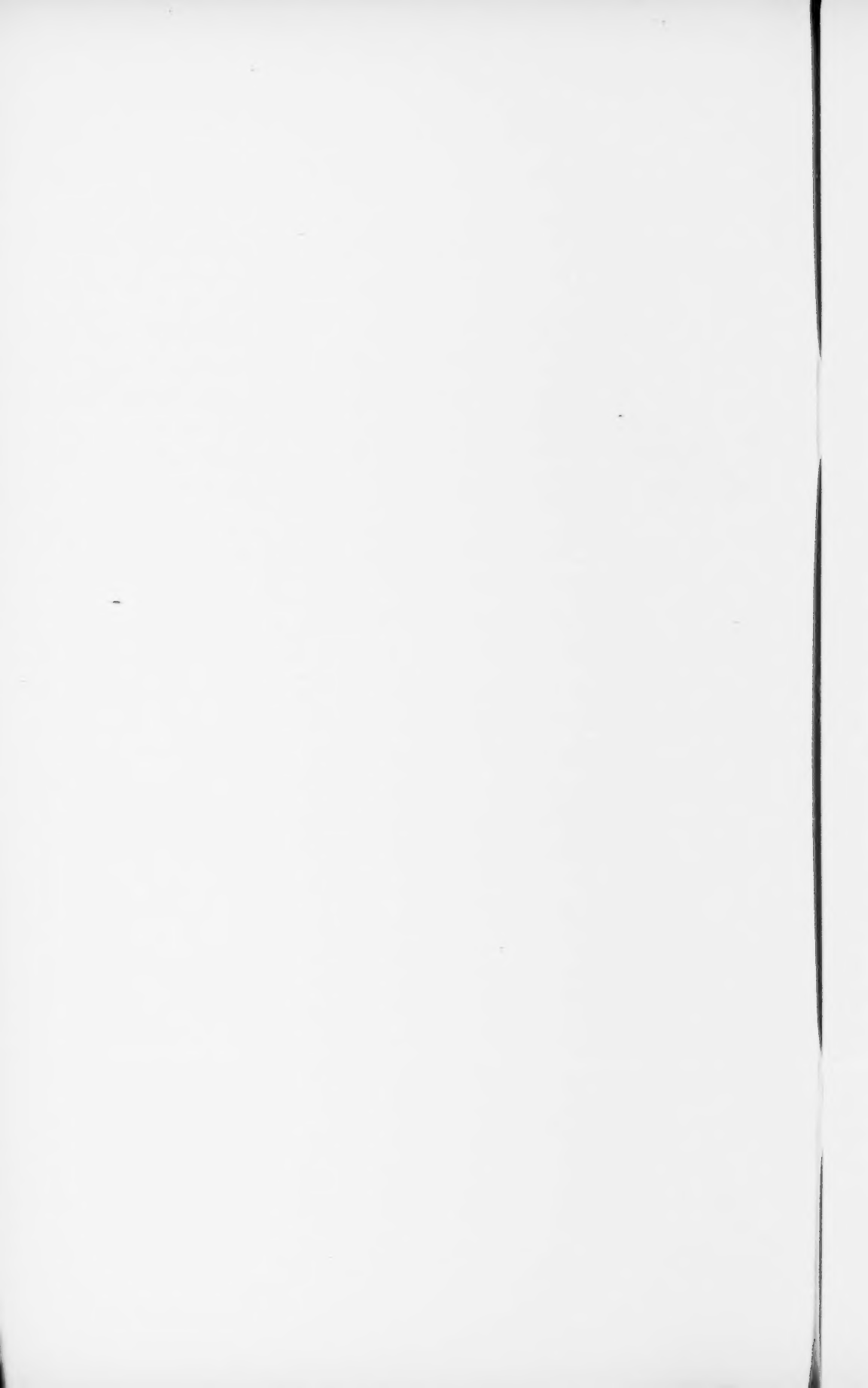
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May 5, 1987



TABLE OF CONTENTS

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| Opinion of the United States Court of Appeals for the Sixth Circuit (February 5, 1987) | A1 |
| Post-Judgment Memorandum Opinion and Order of District Court (June 24, 1985) | A24 |
| Judgment Entry of District Court (May 25, 1985) | A29 |
| Memorandum Opinion and Order of District Court (May 25, 1985) | A31 |
| Opinion of the United States Court of Appeals for the Sixth Circuit (December 11, 1980) | A49 |
| Memorandum Opinion and Order of District Court (October 9, 1979) | A58 |
| 21 U.S.C. §321(w) | A67 |
| 21 U.S.C. §331(a-d) | A68 |
| 21 U.S.C. §332(a-b) | A68 |
| 21 U.S.C. §352(f) | A69 |
| 21 U.S.C. §360b | A70 |
| 21 C.F.R. §201.105 (1986) | A77 |



APPENDIX

**OPINION OF THE UNITED STATES COURT OF
APPEALS FOR THE SIXTH CIRCUIT**

(Decided February 5, 1987)

No. 85-3608

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F.
BAUER, JOHN D. BURROWS, RUSSELL C.
HUMPHREY, JR., SIMON E. MILLER,
IBA, INC., DANIEL BELSITO,
Defendants-Appellants.

[811 F.2d 287]

United States brought action against drug retailers to enjoin distribution of animal drugs that were allegedly misbranded. The United States District Court for the Northern District of Ohio, Thomas D. Lambros, J., determined that Food and Drug Administration lacked authority to promulgate misbranding regulation. The United States appealed. The Court of Appeals, 635 F.2d 564, remanded. Upon remand, the District Court entered judgment for United States. Retailers appealed. The Court of Appeals, Wellford, Circuit Judge, held that: (1) Administration could reasonably require that new animal drugs be sold

in conformity with labels proposed by manufacturer in applications for new animal drug status, and (2) misbranding regulation, which permitted sale of animal drug to veterinarian or only on prescription or other order of veterinarian, required direct communication between veterinarian and drug retailers and was not satisfied by veterinarian giving prescription order to buyer.

Affirmed.

NATHANIEL R. JONES, *Circuit Judge*, concurred in part, dissented in part, and filed opinion.

Before JONES and WELLFORD, *Circuit Judges*, and GILMORE, *District Judge*.*

WELLFORD, *Circuit Judge*

The government obtained an injunction which prohibited defendants-appellants from distributing certain animal drugs on the ground that the drugs were misbranded and not being sold in compliance with 21 C.F.R. § 201.105 (1985). We affirm the holding of the district court with respect to the applicability of section 201.105 to the drug sales in controversy.

Defendants-Appellants in this case are distributors of drugs for use by dairy farmers. They had distributed certain drugs to users without a direct order from a veterinarian. FDA regulations require that some drugs must have a veterinarian's order to be dispensed, 21 C.F.R. § 201.105, and the government contends the drugs at issue fall within those regulations. In November 1978, the government filed a complaint in the lower court seeking an injunction under 21 U.S.C. § 331 (1982) against defendant Jerry Colahan and others. The court issued a temporary

*The Honorable Horace W. Gilmore, United States District Judge for the Eastern District of Michigan, sitting by designation.

restraining order, which was soon replaced by a stipulated order that the defendants would not distribute the drugs without a prescription or other order of a veterinarian.

The defendants then instituted a practice, which came to be called the "slip system," whereby purchasers would aver to the defendants that the drugs were being bought on a veterinarian's order. The buyers signed a form that indicated their name, the drug bought (but not quantity) and the date of purchase. The name of the veterinarian and the date of the order were not indicated on these forms.

On October 9, 1979, on defendant Colahan's motion, the district court dissolved the stipulated order, ruling that the FDA lacked the authority to promulgate section 201.105. That court subsequently enjoined the government from prosecuting a similar action in Massachusetts against defendant IBA, Inc. The Massachusetts action was then transferred to Ohio and consolidated with the Colahan case.

The government appealed the district court's October 9 order and on December 11, 1980, this court reversed, holding that section 201.105 was not invalid and that it was within the agency authority under the statutory scheme. This court remanded the case and directed that the stipulated order be reinstated. See *United States v. Colahan*, 635 F.2d 564 (6th Cir.1980), *cert. denied*, 454 U.S. 831, 102 S.Ct. 127, 70 L.Ed.2d 108 (1981). Upon remand, after further discovery, the parties submitted cross motions for summary judgment, and the district court entered judgment for the government. The district judge issued an order enjoining defendants from distributing the drugs at issue without a direct order from a veterinarian. Thereafter, on defendants' motion and the government's stipulation, the

court exempted the drug Nitrofurazone from the order because it was currently available elsewhere without prescription. The court denied defendants' motion to clarify or stay the injunction. Defendants appealed from that injunctive order.

I.

The government charged that 17 drugs sold by defendants were "misbranded." The violation alleged in this case concerns the manner in which the drugs were sold or distributed with the restrictive labeling on the drugs involved.

Section 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (1982), prohibits the "introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded." 21 U.S.C. § 331(a). A drug is misbranded "[u]nless its labeling bears . . . adequate directions for use. . . ." 21 U.S.C. § 352(f) "Adequate directions for use" are defined in the regulations as "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5.

The statute requiring adequate directions contains a proviso that if such directions are "not necessary for the protection of the public, the Secretary shall promulgate regulations exempting such drug . . . from such requirement." 21 U.S.C. § 352(f). Under this authority the Secretary promulgated 21 C.F.R. § 201.105, which applies only to veterinary drugs. This regulation was held valid in the previous appeal. It provides (in part):

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot

be prepared, shall be exempt from [21 U.S.C. 352(f)(1)] if . . .

(a) the drug is:

(1) . . . to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; . . .

. . .

[and]

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian". . . .¹

21 C.F.R. § 201.105.

Thus, an animal drug that is described in section 201.105, but either is not sold on the "prescription or other order" of a veterinarian or does not bear the cautionary label, is not in compliance with the regulation and, under the statutory scheme outlined above is "misbranded." All of the drugs involved in this case are sold with the cautionary label set out in subsection (b)(1) above. We must determine whether the drugs in question are governed by section 201.105 and, if so, whether they are sold on the prescription or other order of a veterinarian.

II.

The remaining sixteen drugs covered by the injunction in dispute fall into three categories. Fourteen are termed New Animal Drugs (NADs) and these form the

1. This regulation is nearly identical in substance to the statute that governs whether human drugs must bear a cautionary label and be sold only on prescription. See 21 U.S.C. §§ 353(b)(1)(B) & 353(b)(4) (1982).

basis of most of the controversy in this case.² Two others, Calphosan B-12 injectable and epinephrine, will be discussed separately.

A. New Animal Drugs

We first decide whether the fourteen New Animal Drugs (NADs) are governed by section 201.105. The government argues that the drugs fall within section 201.105 and that these drugs are required to bear the cautionary label as part of their approval as NADs.

The FDA's interpretation of the misbranding provision of the Food, Drug and Cosmetic Act, 21 U.S.C. § 352, is that failure to distribute the controverted drugs in accordance with approved prescription labeling rendered the drugs misbranded under 21 C.F.R. § 201.105. In our first consideration of the issues raised by Colahan and other animal drug distributors, we concluded that FDA had the authority to exempt certain animal drugs from a misbranding action if certain prerequisites were satisfied. Deferring to agency expertise, the prior panel found "correct" FDA's interpretation that "under the proviso contained in § 352(f), it may require by regulation, as it has, that such drugs [NADs] are exempt and thus approved for distribution *only* if the requirements of 21 C.F.R. § 201.105 are met since professional direction, in the words of the statute, 'is necessary for the protection of the public health.'" *United States v. Colahan*, 635 F.2d 564, 567 (6th Cir.1980), *cert. denied*, 454 U.S. 831, 102 S.Ct. 127, 70 L.Ed.2d 108 (1981) (emphasis in original). FDA now argues that the

2. The fourteen New Animal Drugs are: Naquasone Bolus, Dexamycin, Dihydrostreptomycin injectable, Oxytocin, Prednisolone injectable, Dexamethasone, Flo-Cillin injectable, Polyflex injectable, BO-SE injectable, Dry-Clox, Gentavet Solution, Heta-cin-K, Chloramphenicol, and Mu-Se injectable. Nitrofurazon, the drug removed from the injunction, is also a New Animal Drug.

drugs in controversy were approved for distribution only if distributors sold the drugs in conformity with the labeling, which required the drugs to be dispensed only on order of a licensed veterinarian. Under the FDA's construction of the key statutory and regulatory provisions, the approved labeling, therefore, rendered the drugs subject to 21 C.F.R. § 201.105, and defendants' refusal to comply with its requirements revoked the drugs' exemption and rendered them misbranded.

We should give proper weight to the construction of the statute by FDA, the agency to whose skill and expertise Congress entrusted the statute's administration. *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 2781-82, 81 L.Ed.2d 694 (1984), *State of Tennessee v. Herrington*, 806 F.2d 642, 653 (6th Cir.1986). When we review an agency's construction and implementation of the statutory scheme that it administers, two questions must be resolved. Initially it is necessary to determine whether Congress specifically resolved the same issue before us. "If the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron U.S.A.*, 467 U.S. at 842-43, 104 S.Ct. at 2781. If Congress failed to address the precise issue in question, the court is not free merely to formulate its construction of the statute. *Id.* at 843, 104 S.Ct. at 2781. Rather the reviewing court must defer to the agency's construction and implementation of its statutory scheme as long as it represents a reasonable and permissible interpretation. *Id.*; see also *Lyng v. Payne*, U.S., 106 S.Ct. 2333, 2341-42, 90 L.Ed.2d 921 (1986). Especially when the statute is complex, as is the one in controversy, the Court has admonished reviewing courts not to substitute their judgment for that of the agency.

Chemical Manufacturers Association v. Natural Resources Defense Council, Inc., 470 U.S. 116, 125, 105 S.Ct. 1102, 1104, 84 L.Ed.2d 90 (1985); see also *Young v. Community Nutrition Institute*,U.S., 106 S.Ct. 2360, 2364, 90 L.Ed.2d 959 (1986).

In this case FDA contends that defendants' failure to comply with the use requirements indicated by the approved NADs' "prescription" labeling renders the drugs as distributed misbranded under 21 U.S.C. § 352(f)(1) and 21 C.F.R. § 201.105. Defendants argue that NAD status, including the requisite label, do not resolve whether the drugs are misbranded under 21 C.F.R. § 201.105. Resolution of these conflicting arguments cannot be made by reference to the statute itself or from legislative history. Since Congress failed to address specifically when an animal drug is deemed misbranded under the statutory scheme, it implicitly delegated to FDA the authority to fill the gap in a reasonable manner. *Chevron U.S.A.*, 467 U.S. at 843, 104 S.Ct. at 2781. To determine whether FDA asserts a permissive statutory construction, a review of the Act and the underlying regulation is in order.

The Food, Drug and Cosmetic Act sets out a "comprehensive scheme for both premarketing clearance and post-marketing regulation of the new animal drugs [by FDA]. . . ." *United States v. An Article of Drug Consisting of 4,680 Pills*, 725 F.2d 976, 981 (5th Cir.1984). In *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973), the Supreme Court delineated FDA's role in reviewing new drug applications:

It is clear to us that FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public. FDA is indeed the administrative agency selected by Congress to admin-

ister the Act, and it cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are 'new drugs'. . . .

* * * * *

. . . Judicial relief is available only after administrative remedies have been exhausted.

Id. at 624, 627, 93 S.Ct. at 2480, 2481.³

Initially the Act "leaves it up to the manufacturer of the animal drug to decide whether its product is subject to the [statutory/regulatory] scheme in the first place."⁴ *Article of Drug*, 725 F.2d at 981. In seeking FDA approval of an NAD, a manufacturer submits an NAD application, proposing labeling to conform to the application. 21 U.S.C. § 360b(a)(1). FDA has the power to determine whether a drug is an NAD unless the manufacturer can show that the drug product does not meet the conditions. *See, e.g., Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795, 802 (2d Cir.1980) (discussing similar provisions for new drugs for human consumption). Under this statutory and regulatory scheme, the manufacturer can avoid FDA regulation by satisfying its burden of showing by tests, laboratory reports, and other scientific

3. *Hynson* involved drugs intended for human consumption, but the agency process for approving new animal drugs is similar.

4. The manufacturer does not need prior FDA approval to market animal drugs that are not NADs as defined at 21 U.S.C. § 360(a)(1). To fall outside of FDA's regulatory power, the drug must be "generally recognized" by qualified experts "as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . . ." *See* 21 U.S.C. § 321(w)(1). If the manufacturer opts not to seek premarketing approval for an animal drug, it runs the risk of being later charged with shipping adulterated animal drugs, in violation of 21 U.S.C. §§ 331(a), 351(a)(5), if or when the Secretary later determines that the manufacturer is producing an NAD which by definition is not recognized generally to be safe and effective.

or medical means that the proposed drug is safe for use without the proposed labeling and is not therefore a new animal drug; or the drug may receive NAD approval if FDA is satisfied by the manufacturer's documentation that the proposed drug is safe for use as directed in the labeling. The statute mandates that FDA refuse to approve applications for drugs that are not shown by the manufacturers to be safe for use as directed in the proposed labeling. 21 U.S.C. § 360b(d). A dissatisfied manufacturer may appeal an adverse ruling to a federal court of appeals. 21 U.S.C. §§ 355(h), 360b(h).

In this case the manufacturer submitted NAD applications for the controverted drugs and included the following cautionary labels: "Federal law restricts this drug to use by or on the order of a licensed veterinarian." This language conforms to that mandated for a particular class of animal drugs exempted from the misbranding provisions in 21 C.F.R. § 201.105. That regulation exempts drugs from misbranding actions despite their potential toxicity if certain preconditions are satisfied. *One requirement mandates that these potentially toxic drugs be labeled to indicate use only on a veterinarian's prescription or other order.* Based upon the manufacturer's submissions and this proposed labeling, FDA approved NAD applications for the drugs in question.

Subsequently, defendants-retailers sold these drugs without veterinary supervision in contravention of the labeling. FDA then brought a misbranding action, reasoning that its approval of these drugs was contingent upon distributors reselling the drugs in conformity with the drugs' labeling, which limited its sale to "prescription or other order of a licensed veterinarian for use in the course of his professional practice. . . ."; defendants' failure to adhere to the restrictions set forth in 21 C.F.R. § 201.105

would, therefore, under FDA's interpretation, render the drugs misbranded. The sole issue becomes whether FDA can reasonably determine that approval of an NAD with labeling, restricting resale of the drugs only upon a licensed veterinarian's order, renders that NAD subject to 21 C.F.R. § 201.105 and the misbranding provisions without requiring FDA to demonstrate the toxicity of the drugs in a misbranding action.

It can be presumed from FDA's approval of these drugs' NAD applications that the drugs in question are safe with the cautionary label. FDA's interpretation of the Act follows logically from this presumption that failure to distribute these drugs in accordance with their labeling, mandating a veterinarian's order, renders the drugs misbranded under 21 C.F.R. § 201.105. The burden is not upon FDA to establish in a misbranding action that the controverted drugs are in fact "not safe for animal use except under the supervision of a licensed veterinarian" because of "toxicity or other potentiality for harmful effect, or the method of its use," 21 C.F.R. § 201.105, when the manufacturer itself proposes the label that states the NAD is not to be used except upon the order of a licensed veterinarian.

The statutory scheme places the burden on the manufacturer in the first instance to show that a proposed NAD is in fact safe for intended use. *See, e.g., Article of Drug*, 725 F.2d 976. Pursuant to 21 C.F.R. § 201.105, FDA may further impose on a manufacturer the additional burden of showing that the proposed labeling and directions permit a layperson to use the drugs safely and properly without veterinary authorization or direction. In this case the manufacturer did not attempt to make that showing but conceded, for whatever reason, that the drugs must be

dispensed only on a prescription or other order of a licensed veterinarian by placing labeling in compliance with 21 C.F.R. § 201.105. FDA may reasonably rely on the manufacturer's concession and mandate that the drugs be sold in conformity with the labeling when it approved the drugs' NAD applications. Defendants should not be permitted to bypass FDA procedures and policies and seek to impose upon FDA the burden of proving a fact which was conceded in the original process by which FDA gave its approval to these NADs for the specific uses under defined conditions.

A reviewing court is not free to substitute its own judgment for that of the agency when the agency has set forth a permissible reading of the statutory scheme. We "need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron U.S.A.*, 467 U.S. at 843 n. 11, 104 S.Ct. at 2782 n. 11. The agency's construction of this complex regulatory scheme is reasonable and therefore permissible.

Defendants are not left without recourse. As the government conceded at oral argument, defendants could apply to FDA for reconsideration of the drugs' veterinary "prescription" requirement, by showing that the drugs lack the "potentiality for harmful effect" if used by laypersons or farmers without the supervision of a licensed veterinarian or that similar drugs are readily available over-the-counter without order of a veterinarian. Accordingly, we affirm the district court's decision that these defendants should be enjoined from attempting to distribute, sell, or use these drugs without the express prescription or other

written order of a veterinarian. We disagree with defendants' contention that new animal drug provisions are irrelevant in a misbranding action of this kind for the reasons stated.

B.

The drugs Calphosan B-12 and epinephrine require a different analysis because they are not approved as NADs as are the fourteen drugs discussed above. They are, however, sold with the cautionary label.

The district court stated that the issue before it was "whether the unapproved animal drug ought to be considered a new animal drug;" that issue, according to the court, turned on whether the drug should be sold only to or on the order of a licensed veterinarian.

These two unapproved drugs, however, bear the same restrictive label as has been discussed concerning the fourteen NADs. The district court granted summary judgment with respect to these two drugs because it determined that there were no material factual issues with respect to the restriction for prescription use only.

In support of the government's motion for summary judgment, it submitted affidavits of two experts and referred to testimony from the Massachusetts hearing on these drugs to establish a scientific basis for the required prescription status of Calphosan and epinephrine. Defendants provided no factual basis to support their position that the two drugs are (or could be) labeled adequately for lay use. Accordingly, we find the district court's injunction with respect to Calphosan B-12 and its declaratory judgment as to epinephrine were appropriate, and we affirm its actions.

III.

We turn now to the question whether the defendants' sales practices violated the regulation.

Section 201.105 requires that the drug be "sold only to or on the prescription or other order of a licensed veterinarian. . . ." 21 C.F.R. § 201.105(a)(1). The government contends, and the trial court held, that this requires a direct communication between the veterinarian and the vendor. The defendants argue that the regulation is satisfied if the "prescription or other order" is given by the veterinarian to the buyer and the buyer assures the vendor (the defendants) that such an order exists. The defendants' "slip system" was instituted to document that they had received such an assurance from the buyer.

The defendants first argue that section 201.105 simply does not state that a veterinarian's order must be given directly to the vendor and the court may not read such a requirement into the regulations. We disagree. The analogous provision for prescription human drugs permits dispensing "only (i) upon a written prescription of a practitioner . . . , or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber. . . ." 21 U.S.C. § 353(b)(1). While this section makes clear that an oral prescription must be communicated directly to the pharmacist, like section 201.105 it does not state that a written prescription must be given to the vendor. Yet it cannot be contended that the mere representation of a buyer of human prescription drugs that he has a prescription would satisfy section 353. The procedures of both 201.105 and 353 are clearly intended to insure that the respective drugs are used only "under

the supervision" of a veterinarian or practitioner. There is no basis for concluding that section 201.105 does not require direct communication where section 353 does. A buyer's statement, even in writing, that he has the order of a veterinarian does not reasonably assure that such an order exists.

The defendants argue that the use of the phrase "prescription or other order of a licensed veterinarian" in section 201.105(a)(1) indicates an intent to permit greater flexibility in the distribution of section 201.105 drugs than of prescription human drugs and therefore the term "other order" should be read to permit orders transmitted through the buyer rather than directly to the vendor. The history of the promulgation of this regulation indicates that, indeed, more flexibility was intended for the sale of section 201.105 drugs, but not of the sort argued for by the defendants. As originally proposed, the predecessor of section 201.105(a)(1) read only "on the order of" and did not contain the words "prescription or other." See 17 Fed. Reg. 1130, 1131 (1952) (proposed February 5, 1952). The agency's response to comments on the proposed regulation contains the following passage:

The American College of Apothecaries and the American Pharmaceutical Ass'n. call attention to the omission of the word "prescription" in subparagraph (1) and to the use instead of "order of a licensed veterinarian." This was done so as not to interfere with the practice, legal in several states, for food stores, animal health stores, and other outlets who do not employ pharmacists to sell restricted drugs on veterinarians' orders. We see no objection to inserting, however, "prescription or other" before "order of a licensed veterinarian."

Memo. of Deputy Comm. of Food and Drugs, April 21, 1952, at 7; II Joint App. 534, 540. Thus, the difference between prescription and order was intended to accommodate the difference between pharmacist and nonpharmacist vendors and not to indicate a relaxation in the manner in which the veterinarian's order could be communicated.

Finally, defendants argue that a requirement of direct communication between veterinarian and vendor is impracticable in an industry in which direct contact with veterinarians is difficult. Dairy farmers should be able, they argue, to obtain a diagnosis and an order for a drug by telephone to the veterinarian and then proceed to the local vendor to purchase the drug. We do not see that the farmer's need for expediency would be significantly hampered by having the veterinarian telephone the farmer's vendor to provide the direct prescription or other order that the regulation requires. The defendants also assert that the farmer's freedom to choose his own vendor will be limited and he will be somehow forced to purchase drugs at greater cost directly from the veterinarian. If such practices are actually engaged in by the nation's licensed veterinarians, we believe there are remedies available in the event of abuse. A requirement that unsafe animal drugs be sold only on the direct order of a veterinarian in order to insure that the veterinarian actually supervises their use does not significantly contribute to the problems defendants predict but does protect the farmers, the animals, and the public that consumes the food products of the livestock against potential harm from improper use or sale of these unsafe drugs. The district court's ruling on this issue is accordingly affirmed.

IV.

In summary, we AFFIRM the actions of the district court with respect to both the NAD and the other two drugs, Calphosan B-12 and epinephrine, and we also AFFIRM its ruling with respect to requiring a written order from a licensed veterinarian for their proper use.

NATHANIEL R. JONES, *Circuit Judge*, concurring in part and dissenting in part.

The majority opinion affirms the district court's decision to enjoin the distribution of certain animal drugs on the ground that the drugs are misbranded because they are not sold in compliance with 21 C.F.R. § 201.105 (1986). For the reasons discussed below, I disagree and would reverse the judgment of the district court. I do, however, concur in Part III of the majority opinion, where the majority affirms the district court's ruling requiring a written order from a licensed veterinarian in order to distribute the challenged drugs.

As discussed in the majority opinion, the district court's injunction covered sixteen drugs falling into three categories. I will first address the appropriateness of the injunction placed on the fourteen New Animal Drugs. Next, I will discuss the injunctions placed on the two other drugs, Calphosan B-12 injectable and epinephrine.

A.

The majority holds that the FDA can "determine that approval of an NAD with labeling, restricting resale of the drugs only upon a licensed veterinarian's order, renders that NAD subject to 21 C.F.R. § 201.105 and the misbranding provisions *without requiring the FDA to demonstrate the toxicity of the drugs in a misbranding action.*" (Maj. op. at 292) (emphasis added). In my view, it is improper

to allow the government to shortcut the proof necessary to show the applicability of section 201.105 to these drugs.

The government did not attempt to show directly that these drugs are ones which "because of toxicity or other potentiality for harmful effect, or the method of [their] use, [are] not safe for animal use except under the supervision of a licensed veterinarian," which is the factual predicate for coverage by section 201.105 as stated in the regulation. Rather, it argued that the drugs fall within section 201.105 solely because they are required to bear the cautionary label as part of their approval as New Animal Drugs. Essentially the government's position is that by virtue of bearing the cautionary label for New Animal Drug purposes these compounds have achieved the status of "prescription animal drugs"¹ and, by that fact alone, they fall within section 201.105 coverage. I find nothing in the statutes or regulations that prescribes this reasoning and I cannot accept it *per se*. I think we must instead determine whether the findings necessarily made during the NAD approval process, and which resulted in a requirement that these drugs bear the cautionary label, collaterally establish the factual predicate of section 201.105 that the drug is unsafe for use without veterinary supervision.

A New Animal Drug is defined as an animal drug that is

- (1) . . . *not generally recognized*, among experts qualified . . . to evaluate the safety and effectiveness of animal drugs, *as safe and effective* for use under

1. Although the government has used the term "prescription animal drugs" in arguments before the district court and throughout its brief, the phrase does not appear in the statutes or regulations. For this reason, and because the phrase supports the government's position through labeling rather than analysis, I do not adopt it.

the conditions prescribed, recommended, or suggested in the labeling thereof; . . . or

(2) . . . [which] has become so recognized but which has not . . . been used to a material extent or for a material time under such conditions. . . .

21 U.S.C. § 321(w) (1982) (emphasis added). Clearly nothing in this definition establishes that, merely by being an NAD, a drug is unsafe for use without veterinary supervision under section 201.105. The most this definition establishes is that the drug is not *recognized* as safe as labeled.

The introduction into interstate commerce of an NAD is prohibited by the Act unless an NAD application has been approved for the drug, and the drug and its labeling conform to the application. 21 U.S.C. §§ 331(a), 351(a)(5), 360b(a)(1) (1982). A manufacturer who seeks NAD approval for a drug must submit, as part of the application, reports of investigations of the safety and effectiveness of the drug and "specimens for the labeling proposed to be used for such drug." 21 U.S.C. § 360b(b)(1) & (6). There are no specific standards that the labeling must meet, but the Secretary is directed to refuse approval of the application if the reports submitted do not show that the drug is safe for use as directed in the proposed labeling. 21 U.S.C. § 360b(d).

The approved application for each of the fourteen NAD's in this case provides that the drug carry the cautionary label. Under the approval scheme outlined above however, the approval of these applications does not amount to a finding by the Secretary that these drugs are unsafe without such a label for two reasons. First, because labeling is proposed initially by the applicant, the Secretary has only to consider whether such labeling is sufficient, not whether it is necessary. The government admits that

more than half of all approved NAD applications do not provide for the cautionary label. The Secretary does not decide what the label should contain, only whether the proposed label is sufficient. It is possible that the applicant for each of these NAD's submitted labeling containing the cautionary label in order to help ease approval, while the Secretary might have approved the drug without the cautionary label if it had been so submitted. Thus, all that can be presumed from the NAD application approval is that the drug is safe with the cautionary label; it does not follow that the label is necessary to make the drug safe.

Second, even if the Secretary had specifically required that these drugs bear the cautionary label, the factual prerequisites of that conclusion are not necessarily the same as those for section 201.105. Assuming that the Secretary has approved these NAD's only if they carry the cautionary label, the reasons for that decision could have been because, at the time of approval, (1) the tests were insufficient to establish whether or not the drug was safe for lay use, (2) the tests although adequate, were inconclusive, or (3) the tests in fact showed that the drugs were unsafe except under supervision of a veterinarian. *See generally* 21 U.S.C. § 360b(d). Section 201.105 requires an affirmative showing that a drug is unsafe for use without veterinary supervision. Only one of several grounds for the Secretary's decision on a NAD approval would establish this required showing.

The collateral use of the NAD status of these drugs as proof that they are unsafe under section 201.105 thus relies on two possibly invalid assumptions: first, that the Secretary actually considered whether or not the drugs required the cautionary label and, if so, second, that the decision was based on a finding that the drugs were in fact unsafe without the label. Additional facts about the

history of the NAD application approval of each of these drugs are necessary in order to validate these assumptions, but have not been presented. The district court accepted the government's argument, and its ruling that the New Animal Drugs are covered by section 201.105 was based solely on the improper collateral use of the NAD application approval. Thus, there was no showing that the drugs are in fact unsafe for use without veterinary supervision. Therefore, I would vacate the injunction as to the fourteen drugs.

B.

The district court stated that the issue before it with regard to Calphosan B-12 was "whether the unapproved animal drug ought to be considered a new animal drug"; that issue, according to the court, turned on whether the drug should be sold only to or on the order of a licensed veterinarian. Both statements are incorrect. First, because many NAD's are approved without the cautionary label, the need for veterinary supervision is not necessary or sufficient for NAD status. Secondly, and more importantly, NAD status does not establish that the drug is unsafe under section 201.105. The government argues that, regardless of these errors, the trial court's finding—that Calphosan should be sold only on the order of a veterinarian—is sufficient to establish the predicate finding required by 201.105. I disagree.

The only evidence considered by the district court and referred to by the government concerning the safety of Calphosan was contained in the affidavit of Dr. Vitolis Vengris and the hearing testimony of Dr. Arthur Aronson. Dr. Vengris, a veterinarian who evaluates drugs for the FDA, stated that Calphosan is a vitamin supplement and that a diagnosis that the supplement is needed can be

made only by a veterinarian with laboratory tests. Unneeded use of the drug, Dr. Vengris stated, "would be wasteful and costly to the owner," and injections "might needlessly expose the animals to possible infections." Dr. Aronson stated only that complex laboratory tests are required to determine if the drug is needed. Neither of these statements go to the finding required by section 201.105: "because of toxicity or other potentiality for harmful effect, or the method of its use, [the drug] is not safe" for use without veterinary supervision. It is not enough that a veterinarian is needed to determine whether the drug is indicated; the regulation is concerned with whether harm will result from unsupervised use. Neither doctor stated that the drug is harmful. Dr. Vengris's statement about the risk of infection is ambiguous. The concern may be based only on the fact that the drug is injected. It does not appear to be the Secretary's position that injected drugs are conclusively unsafe under section 201.105, for at least one drug, epinephrine, is allowed to be sold over the counter in 10-milliliter vials for administration by injection. See 21 C.F.R. § 500.65. This ambiguous statement is not enough to support a finding that the drug is unsafe under section 201.105, and I would vacate the injunction as it relates to Calphosan B-12 as well.

C.

The drug epinephrine is governed by its own regulation. That regulation provides that epinephrine can be sold without a prescription in dosage of 10 milliliters or less. 21 C.F.R. § 500.65 (1986). The government claimed that the defendants dispensed this drug in 30-milliliter vials. The district court ruled, however, that, for lack of evidence, the government was not entitled to summary judgment on the question of whether section 500.65 was violated, and

therefore an injunction could not issue. The court then issued a declaratory judgment that epinephrine was not to be sold in excess of 10-milliliter dosages, citing the declaratory judgment statute, 28 U.S.C. § 2201 (Supp. III 1985).

In essence the court has done no more than declare that section 500.65 applies to the drug and that it prohibits sales in dosages of over 10 milliliters without a prescription. The defendants do not challenge the regulation itself. Consequently, there was no controversy about the issue that the court decided. In absence of an actual controversy, declaratory relief is not proper. See 28 U.S.C. § 2201(a); *Jervis B. Webb Co. v. Southern Systems, Inc.*, 742 F.2d 1388, 1399 (Fed.Cir.1984). Therefore, I would also vacate the order as it relates to epinephrine.

**POST-JUDGMENT MEMORANDUM OPINION AND
ORDER OF THE UNITED STATES DISTRICT
COURT**

(Filed June 24, 1985)

Nos. C 78-1470A and C 80-472A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

v.

IBA, INC., *et al.*,
Defendants,

UNITED STATES OF AMERICA,
Plaintiff,

v.

JERRY J. COLAHAN, *et al.*,
Defendants.

POST-JUDGMENT MEMORANDUM OPINION
AND ORDER

LAMBROS, *District Judge*

On May 25, 1985 judgment was entered in these actions enjoining defendants from introducing certain veterinary drugs into the stream of interstate commerce. Defendants now move to stay that judgment pending appeal and ask the Court to reinstate the November 9, 1978

stipulated order that has governed the distribution of the drugs at issue since the initiation of these actions. Additionally, defendants seek clarification of the Court's ruling that defendants have failed to comply with the provisions of 21 C.F.R. §201.105.

In the May 25, 1985 memorandum opinion and order accompanying the Court's judgment in these actions, it was determined that the slip system used by defendants to distribute the drugs at issue fails to comply with the requirement of 21 C.F.R. §201.105 that such drugs be sold "only to or on the prescription or other order of a licensed veterinarian. . . ." Defendants assert that the Court's ruling provides them with no guidance as to what type of "order" other than a prescription will satisfy the mandate of the regulation. The meaning of the Court's order with respect to this issue is perfectly clear—21 C.F.R. §201.105 requires direct communication between a veterinarian and the dispenser of the drug. This communication may take the form of a prescription or any other oral or written instruction from a veterinarian that is provided directly to the drug distributor. The slip system employed by defendants does not necessitate the requisite direct communication from a veterinarian to the dispenser, but permits the distribution of regulated drugs solely on the assertion of a customer that he has received a veterinarian's order. Consequently, the Court concluded that this system violates 21 C.F.R. §201.105. Inasmuch as the Court's ruling on this issue is set forth with lucidity in its May 25, 1985 memorandum opinion and order, defendants' motion for clarification is denied.

Defendants seek a stay of the Court's judgment pending appeal pursuant to Fed. R. Civ. P. 62(c). In order to establish that they are entitled to a stay of judgment, defendants bear the burden of showing: (1) that they

are likely to succeed on the merits of the appeal; (2) that they will suffer irreparable injury unless a stay is granted; (3) that no substantial harm will come to other interested parties; and (4) that a stay will do no harm to the public interest. *Reed v. Rhodes*, 549 F.2d 1046, 1048 (6th Cir. 1976). Defendants contend that because of the complexity of the issues presented in these actions, there is a substantial probability that they will prevail on appeal. Although the issues raised in these cases are indeed complex, the United States Court of Appeals for the Sixth Circuit has already provided some indication as to how it is likely to rule on these cases. In considering an appeal previously filed in *United States v. Colahan*, the Court of Appeals found that the Food and Drug Administration (FDA) was authorized to promulgate 21 C.F.R. §201.105 pursuant to the provisions of §502 of the Food, Drug, and Cosmetic Act (Food and Drug Act), 21 U.S.C. §352(f). The Court of Appeals stated in that decision that “[i]mplementation of the [Food and Drug] Act’s complex statutory scheme is a job entrusted in the first instance to the FDA. Therefore, since there is more than one reasonable interpretation of this statute, the court should follow the interpretation urged by the FDA.” *United States v. Colahan*, 635 F.2d 564, 567-68 (6th Cir. 1980). Thus, the Sixth Circuit has clearly expressed a willingness to provide the FDA with wide discretion in executing and enforcing the regulatory scheme established under the Food and Drug Act. Given these pronouncements by the Court of Appeals, this Court cannot conclude that there is a sufficient likelihood that defendants will prevail on appeal so as to warrant the issuance of a stay.

Defendants also contend that the Court’s judgment should be stayed in order to prevent irreparable harm to their business. Although the brief supporting defendants’

motion to stay contains several broad assertions concerning the adverse effect that the Court's judgment will have on their business, defendants have provided no specific information or economic data indicating the extent to which their business will be impaired by the Court's ruling. Defendants have therefore failed to meet their burden of demonstrating that they will suffer irreparable injury in the absence of a stay. Additionally, a consideration of the public interest as it relates to these cases does not support the issuance of a stay. These cases involve the distribution into interstate commerce of drugs which the FDA considers to be dangerous unless sold under the supervision of a veterinarian. The Court has determined that the system employed by defendants to dispense these drugs does not comply with the regulatory scheme promulgated by the FDA pursuant to the Food and Drug Act. A stay of judgment would therefore subject the public to an unreasonable risk of exposure to drugs which the FDA has concluded to be dangerous. Defendant's motion for a stay of judgment pending appeal is denied.

Defendants also seek a reinstatement of the November 9, 1978 stipulated order governing the distribution of these drugs pending appeal. In view of the fact that the Court has rendered a final judgment with respect to these actions and has determined a stay of that judgment should not be issued, there is no reason to warrant the reinstatement of the November 9, 1978 stipulated order. Accordingly defendants' motion to reinstate the November 9, 1978 order is denied.

In support of their motion to stay, defendants have submitted the affidavit of Mr. Daniel J. Belsito, president of IBA, Inc. In that affidavit Mr. Belsito avers that the drug Nitrofurazone Solution is now permitted to be sold over the counter without a prescription. Upon stipulation

by the government that this drug is presently permitted to be sold without a prescription, Nitrofurazone Solution shall be exempted from the dictates of the Court's May 25, 1985 judgment.

In summary, defendants' motions for clarification, stay of judgment, and reinstatement of the November 9, 1978 stipulated order are each denied.

IT IS SO ORDERED.

/s/ THOMAS D. LAMBROS

United States District Judge

**JUDGMENT ENTRY OF THE UNITED STATES
DISTRICT COURT**

(Filed May 25, 1985)

Nos. C 78-1470 and C 80-472A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

v.

JERRY J. COLAHAN, *et al.*,
Defendants,

UNITED STATES OF AMERICA,
Plaintiff,

v.

IBA, INC., *et al.*,
Defendants.

JUDGMENT

LAMBROS, *District Judge*

In accordance with the memorandum opinion and order issued this day in the above-styled causes, wherein decisions were rendered upon cross motion for summary judgment, the defendants are hereby enjoined from introducing the following veterinary drugs into the stream of interstate commerce: Naquasone Bolus; Dexamycin, Dihydrostreptomycin injectable; Oxytocin; Prednisolone in-

jectable; Dexamethasone; Flo-Cillin injectable; Polyflex injectable; BO-SE injectable; Dry-Clox; Gentavet Solution; Hetacin-K; Chloramphenicol; Nitrofurazon Solution; Mu-Se injectable; and Calphosan B-12 injectable. Defendants shall cease and desist distribution of these drugs until it is established by defendants that the manner in which they market the enumerated drugs complies with 21 C.F.R. §201.105.

It is further ordered that, epinephrine may not be sold by defendants without a prescription or other order of a veterinarian in dosage units of greater than 10 milliliters;

It is further ordered that defendants Robert L. Berkshire and Ralph A. Sharver are dismissed from these actions.

It is further ordered that the motion of defendants for sanctions against the United States is denied.

These rulings on cross motion for summary judgment are dispositive of all issues.

Accordingly, this action is terminated.

IT IS SO ORDERED.

/s/ THOMAS D. LAMBROS

United States District Judge

**MEMORANDUM OPINION AND ORDER OF THE
UNITED STATES DISTRICT COURT**

(Filed May 25, 1985)

Nos. C 78-1470 and C 80-472A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

v.

JERRY J. COLAHAN, *et al.*,
Defendants,

UNITED STATES OF AMERICA,
Plaintiff,

v.

IBA, INC., *et al.*,
Defendants.

MEMORANDUM OPINION AND ORDER

LAMBROS, *District Judge*

These actions were instituted by the United States under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-392. to enjoin the introduction by defendants of certain allegedly misbranded veterinary drugs into the stream of interstate commerce. Defendants are: Independent Buyers Association, Inc., (IBA), a Massachusetts corporation; Daniel J. Belsito, the president of IBA; and seven

Ohio residents—Jerry J. Colahan, Norman F. Bauer, Robert L. Berkshire, John D. Burrows, Russell C. Humphrey, Jr., Simon E. Miller, and Ralph A. Scharver—all seven of whom the government alleges are engaged in the retail distribution of misbranded veterinary drugs. At issue are cross motions for summary judgment and defendant's motion for sanctions against the United States. Also pending is the motion of defendants Robert L. Berkshire and Ralph Scharver to be dismissed from Case No. C 78-1470 because they are no longer affiliated with IBA.

"The Federal Food, Drug, and Cosmetic Act . . . provides a comprehensive scheme to protect the public from drugs that may be unsafe or ineffective for their intended uses." *United States v. An Art. of Drug Con. of 4680 Pails*, 725 F.2d 976, 978 (5th Cir. 1984). As a part of this scheme, the Act regulates the marketing of drugs used in treating animals which are raised for human consumption or whose by-products are consumed by humans. *Id.* The government contends that defendants are marketing certain veterinary drugs in a manner that causes these drugs to be misbranded within the meaning of §502(f)(1) of the Act, 21 U.S.C. §352. Defendants deny that these drugs are misbranded.

Section 352 provides: "A drug or device shall be deemed to be misbranded . . . (f) unless its labeling bears (1) adequate directions for use. . . ." Food and Drug Administration (FDA) regulations define adequate directions for use as "[D]irections under which [a] layman can use a drug safely and for the purposes for which it is intended. 21 C.F.R. §201.5.

The drugs marketed by defendants fall into two broad categories, new animal drugs and unapproved animal drugs.

The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, - (i) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof. . .

Title 21 U.S.C. §321(w). The Act establishes a system of premarketing clearance for new animal drugs by prohibiting their introduction into interstate commerce unless a Food and Drug Administration (FDA) approved New Animal Drug Application (NADA) is in effect for that drug. See 21 U.S.C. §§360b(a)(1)(A) and *United States v. An Art. of Drug. Con. of 4680 Pails*, 725 F.2d 976, 978 (5th Cir. 1984). FDA approved NADA's are in effect for the new animal drugs in issue here. NADA approval was obtained from FDA by the various manufacturers of the drugs prior to these drugs becoming available to distributors, such as the defendants, for interstate sale. An approved NADA establishes the terms and conditions under which a given new animal drug may be marketed. The defendants were not a party to the various proceedings where FDA approved NADA's for the drugs in issue here.

"A drug that is not a new animal drug can be marketed without FDA approval." *Id.* at 980. "For a drug not to be considered a new animal drug, it must be "generally recognized" by qualified experts as safe and effective for each of its intended uses. 21 U.S.C. §321(w)." *Id.* Two of the drugs in issue here that are marketed by defendants, epinephrine and calphosan B-12, are not new

animal drugs. These drugs are referred to herein as unapproved animal drugs.

The government alleges that the new animal drugs and sold by defendants are misbranded because the defendant's marketing practices with respect to these drugs do not conform to FDA regulations, which provide in pertinent part:

A drug intended for veterinary use which because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from [21 U.S.C. §352 (f)] if all of the following conditions are met:

a. The drug is:

1. In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

2. In the possession of a licensed veterinarian for use in the course of his professional practice.

b. The label of the drug bears:

1. The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

21 C.F.R. §201.105. If a new animal drug satisfies the conditions set forth in 21 C.F.R. §201.105 it is exempt from the labelling requirement under 21 U.S.C. §352. It is the

contention of the government that the new animal drugs in issue here are not marketed in accordance with 21 C.F.R. §201.105 and are thus misbranded.

These cases began as separate actions. *United States v. I.B.A., Inc.*, Case No. C 80-472A, was instituted in the District Court of Massachusetts. *United States v. Jerry J. Colahan*, Case No. C 78-1470 was initiated in the Northern District of Ohio. Because of the relationship between the defendants, these cases were consolidated on the docket of this Court. The defendants in the Ohio case, C 78-1470, are the contractually constituted distributors of IBA veterinary drugs in the Ohio area. Additionally the issues raised in the Massachusetts case are related to the issues raised in the Ohio case.

The government has moved for summary judgment in Case No. C 80-472A, *United States v. IBA, Inc.* According to the government, it has limited its motion to this case because IBA, Inc., is the source of the veterinary drugs distributed by the defendants in C 78-1470, *United States v. Colahan*. It is the view of the government that the sweep of the decision in the IBA case will embrace the defendants in the Colahan case.

Defendants have moved for partial summary judgment and have made their motion applicable to both cases. The defendants have also filed briefs in opposition to the summary judgment motion of the government.

Oral arguments were heard in relation to the motions of both parties on February 1, 1985.

Summary judgment may be granted only if it appears from pleadings, depositions, admissions and affidavits, considered in the light most favorable to the nonmoving party that there is no genuine issue as to any material fact and

that the moving party is entitled to judgment as a matter of law. See Fed. R. Civ. Proc. 56(e); *Potter v. Columbia Broadcasting System, Inc.*, 368 U.S. 464 (1962). The party against whom the motion is directed is obliged to set forth facts raising genuine issues of material fact. *Berst v. Adolph Coors Co.*, 650 F.2d 930 (8th Cir. 1981). Conclusory and unsupported allegations do not meet a nonmoving party's burden of showing genuine issues of fact. *Bryant v. Commonwealth of Kentucky*, 490 F.2d 1273 (6th Cir. 1974).

The first issue raised by the respective motions for summary judgment is whether a defendant may challenge in this action the FDA requirement that an approved new animal drug carry on its label the words "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian," on the ground that the caution label is unnecessary and/or that the drug is available for sale without the caution label or must such challenges be raised before the FDA by the manufacturer of such drug or any person that seeks to question the drug's status? Defendants argue that a challenge to the caution label requirement should be permitted in this Court because caution labels are frequently affixed to new animal drugs voluntarily by animal drug manufacturers and not because of FDA compulsion. Defendants also contend that they should be permitted to challenge the caution label requirement in this Court because they were not parties to the various administrative proceedings where FDA established the condition that a caution label must be affixed to the new animal drugs in issue. The government has stated that the failure of defendants to support this aspect of their motion with specific evidence indicating that the manufacturers voluntarily placed certain labels on these drugs renders defendants position on this issue of mere

request for an advisory opinion. The government has stated in the alternative, that this Court does not have jurisdiction to determine whether the caution label requirement imposed by FDA is valid.

A decision as to whether these defendants may challenge the FDA requirement that caution labels be placed on the veterinary drugs in issue here is not an advisory opinion. The scope of this decision however must be confined to the controversy before the court. In this context, the FDA has required the manufacturers of the new animal drugs that defendants market to place caution labels on these drugs. The FDA imposed this requirement as a part of its authority under the Act to prohibit the introduction into interstate commerce of any new animal drug unless the Food and Drug Administration has approved a new animal drug application in relation to it. Thus, the requirement to place a caution label on these drugs stems from their status as new animal drugs. See, 21 U.S.C. §360(b). "The heart of the . . . procedures designed by Congress [for the regulation of new animal drugs] is the grant of primary jurisdiction to FDA, the expert agency it created." *Weinberger v. Hynson, Westcott, and Dunning*, 412 U.S. 609, 627 (1973)." "FDA does not have the final say, for review may be had, not in a district court, but a court of appeals." *Id.* The purpose of the new animal drug application process is to protect the public against danger to human life arising from use of unsafe and ineffective drugs by assuring that before any drug is marketed it will have been carefully reviewed by FDA. *Premo Pharmaceutical Laboratories v. United States*, 629 F.2d 795, 802 (2d Cir. 1980). The FDA has reviewed the new animal drugs in issue here and determined that given the level of safety and effectiveness of these drugs, it is required they must bear the caution legend. It is not for a

district court to second guess this determination. “[Such a] determination necessarily implicates complex chemical and pharmacological considerations.” *Id.* at 814. Such considerations are not within the conventional experience of district courts. The FDA is better equipped by reason of its expertise to make these determinations. See *Far Eastern Conference v. United States*, 342 U.S. 576 (1952).

This is not to say that a district court may never determine that a caution legend is unnecessary. For instance, in situations where the FDA has not passed on the question of whether a drug should be considered a new animal drug and required to bear the caution legend a district court has jurisdiction to decide whether the drug should be considered a new animal drug. See *United States v. Western Serum Co., Inc.*, 498 F. Supp. 863 (D. Ariz. 1980). In exercising this jurisdiction the Court should determine whether there is “*general recognition*” among experts that a given drug is safe and effective. If it is found that a drug is generally recognized as safe and effective, then it may be held that this drug is not a new animal drug and the district courts have jurisdiction to permit marketing of the drug without FDA approval or a caution label. *United States v. An Act of Drug Con. of 4680 Pails*, 725 F.2d 976, 980 (5th Cir. 1984). This is not the case here. In this case the FDA has already designated these drugs as new animal drugs. Under the rule set forth in *Weinberger v. Hynson, Westcott, and Dunning*, 412 U.S. 609 (1973) a district court may not review this determination. Review must be obtained at the circuit court level.

The defendants have pointed out that the right to judicial review of the NADA's involved in these cases has been lost because the time for seeking circuit court review

under the statute has expired. Thus, the defendants argue unless review is granted in this forum the right to judicial review is unavailable.

Where a dispute exists as to whether a drug product is "generally recognized" by the experts to be safe and effective, [a] district court [may determine] that issue, not whether the product is in fact safe and effective. The latter issue is to be determined by the FDA which as distinguished from a court, possesses superior expertise usually of a complex scientific nature, for resolving the issue. *Premo Pharmaceuticals Laboratories v. United States*, 629 F.2d 795, 803 (2d Cir. 1980).

Under the above approach a defendant may present evidence in district court concerning whether there is general recognition among experts as to the safety and effectiveness of a new animal drug. The Court need not consider the complex chemical and pharmacological aspects of this issue or whether the drug is actually safe and effective. It is only necessary to determine from the evidence whether there is *general recognition* among experts concerning the drug's safety and effectiveness (emphasis supplied). A determination that a drug is generally recognized as safe and effective would free the drug from new animal drug status and the requirement that the drug bear a caution label. The availability of this procedure enables a defendant that is the subject of a FDA enforcement action to challenge the new animal drug status of a substance without being required to go to FDA, the agency that is suing the defendant, in order to contest the new animal drug designation. It also mitigates the seeming harshness of the situation where the drug's sponsor did not seek judicial review and the statutory period for any other

person to seek review has expired. The Act provides for the district courts and FDA to share some of the responsibility for NADA determinations. The major distinction between court and agency functioning in this regard is that the courts do not determine whether a drug is actually safe and effective, but only whether there is a general recognition among experts concerning a drug's safety and effectiveness.

The defendants have failed to demonstrate that there is a genuine issue of material fact as to the general recognition among experts of the safety and effectiveness of any of the new animal drugs which they market. Defendants have presented no evidence of expert opinion to support this contention. On the other hand following regulatory proceedings conducted by FDA, each of these drugs has been designated as a new animal drug. Under these circumstances the government is entitled to a judgment as a matter of law that the new animal drugs marketed by IBA are required to bear the caution legend and be designated as new animal drugs within the meaning of 21 U.S.C. §321(w).

The second issue presented in the motions for summary judgment is whether a veterinary drug which has a caution label is misbranded within the meaning of the relevant statutes if it also carries sufficient instructions for such drug's application and usage such that a reasonably prudent ultimate user could administer the drug. A new animal drug is one which is not generally recognized by experts as safe and effective. Title 21 U.S.C. §321(w), see also *Cutler v. Kennedy*, 475 F. Supp. 838, 842 (D.C.D.C. 1979). The regulations which implement the Food, Drug, and Cosmetic Act, 21 U.S.C. §301, et seq state that adequate directions for use can not be written for unsafe drugs.

See 21 C.F.R. §201.105. Read together, the plain meaning of the language within 21 U.S.C. §321(w) and 21 C.F.R. §201.105 is that adequate directions for use can not be written for a drug that is not generally recognized by experts as safe and effective.

Title 21 C.F.R. §201.105 sets forth the conditions that must be satisfied in order to exempt a drug for which adequate directions for use cannot be prepared, from the labelling requirements of the Act. It has been determined that Congress has vested the FDA with the authority to promulgate these regulations. See *United States v. Colahan*, 635 F.2d 564 (6th Cir. 1980). Thus, whether a new animal drug is misbranded can only be determined by comparing how the drug is marketed to the marketing standards established under 21 C.F.R. §201.105. This comparison is closely related to the third issue that the parties address in their respective motions for summary judgment and is discussed in the succeeding paragraphs.

The third issue is whether a sale of a new animal drug be made "on the prescription or other order of a licensed veterinarian" pursuant to 21 C.F.R. §201.105, by any means other than upon a prescription slip of a veterinarian or direct contact by such veterinarian with the drug's vendor. Title 21 C.F.R. §201.105 provides that a new animal drug must be "sold only to or on the prescription or other order of a licensed veterinarian. . . ." The defendants have stated that the plain meaning of this provision is that a prescription is not necessary and the order of a licensed veterinarian will satisfy the regulation. In this connection the defendants employ a slip system. The defendant's slips are statements which IBA dealers obtain from customers. The slips are in the following form:

I, request to purchase these drugs
 based on an order from a veterinarian
 (Drug names listed here).
 (Signature) (Date)

It is the contention of the defendants that if a "slip" is obtained from a customer, that obtaining this slip constitutes compliance with the requirement of 21 C.F.R. §201.105 that drugs be sold only to or on the order of a licensed veterinarian.

As stated earlier, "[E]ffect must be given to the plain meaning of statutory language." *Caminetti v. United States*, 242 U.S. 471 (1971). It is clear from 21 C.F.R. §201.105 (a) (1) that it is not necessary that a written prescription from a veterinarian accompany every sale of animal drugs. The regulation clearly provides for a sale on the "other order" of a licensed veterinarian. It is clear from the plain language in the regulation that the order must originate from a veterinarian. Nothing else can be considered the order of a veterinarian.

The defendant's slip system does not satisfy the condition established under 21 C.F.R. §201.105(a) (1) concerning an order of a veterinarian. In effect, the slip that defendants require from their customers is actually the order of the customer. The slips do not even require that the name of the prescribing veterinarian be disclosed. There is too much room for misrepresentation under the slip system for it to pass muster. "It is well established that the task [of the court's] in interpreting a single act is to give the Act the most harmonious, comprehensive meaning possible in light of the legislative policy and purpose." *Weinberger v. Hynson, Westcott and Dunning*, 412 U.S. 609, 631 (1973). A system that allows a consumer to simply assert that a veterinarian has directed the pur-

chase of highly toxic or unsafe drugs can not be reconciled with the language in 21 C.F.R. §201.105(a)(1) or the purpose of the Food, Drug, and Cosmetic Act. Reasonable minds can come to but one conclusion as to the propriety of the defendant's slip system. The slip system is violative of the regulatory criteria set forth in 21 C.F.R. §201.105 (a)(1). The government is entitled to a judgment concerning this issue as a matter of law.

The fourth issue is whether the distributors of the defendants products are regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale and retail distribution of veterinary drugs as required under 21 C.F.R. §201.105. In order to determine whether one is "regularly and lawfully engaged" in the distribution of drugs, it has been the practice of FDA to require that these persons are licensed under state law. The government has asserted that numerous IBA dealers are not properly licensed under state law. It is the government's contention that where it is shown that an IBA dealer is not licensed under state law, that the failure to obtain proper licensing constitutes non compliance with 21 C.F.R. §201.105.

It is not necessary to determine the fourth issue in order to resolve these motions for summary judgment. Assume *arguendo* that all IBA distributors are regularly and lawfully engaged in the distribution of drugs. IBA would still be in violation of the provisions in 21 C.F.R. §201.105(a)(1) because of the deficiencies in the IBA slip system. Title 21 C.F.R. §201.105 requires satisfaction of all of the conditions enumerated within it in order to qualify for an exemption from 21 U.S.C. §352(f)(1). Inasmuch as the defendant's slip system violates an aspect of 21 C.F.R. §201.105, the defendants are in violation of the entire regulation. See 21 C.F.R. §201.105. It is there-

fore unnecessary to undertake a lengthy state by state analysis of the various state licensing requirements to which IBA must conform.

It is well settled that before an injunction may be issued under 21 U.S.C. §332 the government must demonstrate that the Act has been violated in a meaningful and ongoing way that is likely to result in public harm. *United States v. Diapulse Corp. of America*, 457 F.2d 25 (2d Cir. 1972). The government has demonstrated through the affidavits of FDA inspectors and IBA dealers, that new animal drugs are being sold to end users under the IBA slip system. This system is deficient as a matter of law in that it does not meet the requirement of 21 C.F.R. §201.105 that drugs be sold only to or on the order of a licensed veterinarian. The motion of the government for a summary judgment in relation to the new animal drugs marketed by the defendant is therefore granted. The motion of the defendants for a summary judgment in relation to these drugs is denied. IBA is hereby enjoined from the introduction of the new animal drugs in issue here into interstate commerce.

The government has also moved for a summary judgment in relation to two unapproved animal drugs that are marketed by the defendants, epinephrine and calphosan B-12. The government has alleged that IBA, Inc. is selling epinephrine in unit dosages greater than 10 milliliters without a prescription in violation of 21 C.F.R. §500.65. The government has also alleged that IBA, Inc. is selling calphosan B-12 without prescriptions.

The record in case C80-472A, *United States v. IBA, Inc.* and the brief of the government have been reviewed for evidence of the quantity of epinephrine sold by IBA. No reference is contained in the government's brief to a basis

in the record for the assertion that IBA sells epinephrine without a prescription in quantities in excess of 19 ml. Therefore, on the basis of the record in this case, the government can not be granted a judgment as a matter of law in relation to defendants' epinephrine marketing practices. However, FDA regulations are clear concerning the amount of epinephrine that may lawfully be sold without a prescription. FDA Regulations provide plainly in pertinent part:

(b) [T]he Commissioner of Food and Drugs has concluded that it is in the public interest to make epinephrine injection 1:1,000 available for sale without a prescription provided that it is packaged in vials not exceeding 10 milliliters and its label bears in addition to other required information, the following statement in a prominent and conspicuous manner: "For emergency use in treating anaphylactoid shock . . . inject subcutaneously."

Although the United States has failed to establish that it is entitled to an injunction, the absence of a factual dispute regarding epinephrine in this case renders it appropriate to accord declaratory relief to the government on this issue. *See* 28 U.S.C. §2201. It is therefore ordered, that epinephrine may not be sold in dosage units in excess of that amount set forth in 21 C.F.R. §500.65, to wit: 10 milliliters.

The United States contends that IBA should restrict its sales of calphosan B-12 to veterinarians or for use under veterinary supervision. Toward this end, the United States has moved for an injunction that will prohibit IBA sales of calphosan B-12 unless the drug is sold in containers that bear a "caution" label. The United States has moved for summary judgment regarding this issue.

Defendants oppose the motion for summary judgment on the ground that the testimony of Vitolis E. Vengris, D.V.M., Ph.D. and Dr. Arthur Aronson, Professor Veterinary Pharmacology at Cornell University, as reflected in their affidavits that are appended to the government's motion, refutes the position of the government that if, "a [drug] bears a [caution label] it automatically cannot be administered by a layman." *Defendants' brief* at 10. IBA argues that this testimony contradicts the position of the government concerning the import of a caution legend, making it inappropriate to decide this issue in a summary judgment context. IBA contends that an evidentiary hearing must be held to consider the calphosan B-12 issue.

Under the regulatory scheme enacted pursuant to the Act, when an injunction is sought by FDA in relation to an unapproved animal drug, this initiative is in some cases tantamount to a request for a determination as to whether the unapproved animal drug ought to be considered a new animal drug. This is the situation here. A review of the affidavits of Dr. Aronson and Dr. Vengris, clearly demonstrates that these doctors agree that B-12 injectable drugs like Calphosan B-12, should be used only by or on the order of a licensed veterinarian. Defendants have produced no evidence whatsoever to rebut this testimony. Hence there is not a genuine dispute concerning the material issue of whether there is general recognition among experts as to the safety and effectiveness of Calphosan B-12; Drs. Aronson and Vengris agreed it should be sold only to or on the order of a licensed veterinarian. This is the only evidence in the record concerning the issue. It is determined therefore that Calphosan B-12 should not be marketed as an unapproved animal drug, but should be considered a new animal drug to be sold subject to terms and conditions established by FDA in

connection with a NADA. The motion of the United States in relation to Calphosan B-12 is granted.

IBA, Inc. has asserted in its motion for summary judgment that it intends to challenge at trial the constitutionality of the veterinary drug regulatory framework. The constitutional arguments asserted in defendants' motion have been reviewed. To the extent that these arguments attack the incorporation of state law into the regulations that are relevant to this action, these arguments are without merit because the violations of IBA arise from its slip system, not failure to comply with state law. Thus, the state law issue is not before this Court. Moreover, the validity of these regulations has been long established. These regulations have been considered by federal courts on numerous occasions. In each instance they have withstood scrutiny. Hence, it is my view that the regulatory scheme operative in these actions is constitutionally valid and that no arguable basis exists for a constitutional challenge. It is therefore unnecessary to conduct further evidentiary proceedings or hearings to address these issues.

IBA has also moved for sanctions against the government on the grounds that the government violated the May 10, 1982 order of this Court that prohibited the government from using information learned through discovery in these cases as a basis for the continued investigation of IBA activities. In support of its motion for sanctions IBA has provided the affidavits of the following IBA distributors: Milton Brandow, K. William Allen, and John D. Bailey. The government has denied that it used information learned in the course of this litigation as a basis for investigations of IBA. In support of the government's response are various affidavits of FDA inspectors.

The weight of the evidence adduced does not support a finding that the government has violated this Court's May

10, 1982 order and used information learned in this litigation to the detriment of IBA. The motion of IBA for sanctions is therefore denied and overruled.

IBA has also moved to dismiss two of the defendants in case no. C 78-1470A, *United States v. Colahan*, Robert L. Berkshire and Ralph A. Scharver, on the grounds that these individuals are no longer affiliated with IBA. The government has filed no opposition to this motion. It is hereby determined basis of the representations of counsel for IBA, no opposition having been filed by the government, that Robert L. Berkshire and Ralph A. Scharver are hereby dismissed as defendants in case no. C 78-1470A, *United States v. Jerry J. Colahan*.

This action is terminated.

IT IS SO ORDERED.

/s/ THOMAS D. LAMBROS

United States District Judge

**OPINION OF THE UNITED STATES COURT OF
APPEALS FOR THE SIXTH CIRCUIT**

(Decided December 11, 1980)

No. 79-3767

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

v.

JERRY J. COLAHAN, *et al.*,
Defendants-Appellees.

[635 F.2d 564]

Government brought suit against veterinarians, alleging that they sold veterinary drugs directly to dairy farmers without a prescription in violation of a regulation promulgated by the Food and Drug Administration. The parties stipulated to an order in which defendants agreed not to distribute nine drugs until further order of the court. Thereafter, the United States District Court for the Northern District of Ohio, Eastern Division, Thomas D. Lambros, J., granted a defense motion to vacate the stipulated order, and the Government appealed. The Court of Appeals, Bailey Brown, J., held that: (1) the district court's action in granting motion to vacate the stipulated order was appealable, and (2) the district court erred as a matter of law in dissolving the stipulated order; defendants' interpretation of the Federal Food, Drug, and Cosmetic Act would require that the FDA either allow un-

restricted over-the-counter sale of all veterinary drugs, or withdraw useful drugs from the market that the FDA considers to be dangerous unless sold by prescription.

Remanded with instructions.

Before MERRITT and BROWN, *Circuit Judges*, and GUY, *District Judge*.*

BAILEY BROWN, *Circuit Judge*.

The government brought this action against Colahan and others (herein collectively referred to as Colahan), alleging that Colahan sold veterinary drugs directly to dairy farmers without a prescription in violation of an applicable regulation promulgated by the Food and Drug Administration (FDA). The district court issued a temporary restraining order. This was replaced six days later by a stipulated order in which Colahan agreed not to distribute nine veterinary drugs until further order of the court. Colahan moved the court after about two months to vacate the stipulated order on the ground that FDA did not have authority to require a prescription in connection with the sale of these drugs. Almost a year later, the district court, recognizing that the question before it was whether the FDA had authority to promulgate the regulation upon which it relied and concluding that FDA did not have such authority, granted the motion to vacate. The district court denied the government's motion to reconsider, denied a certification under 28 U.S.C. § 1292(b), and denied a stay pending appeal. The government now appeals.

The government's appeal raises two issues. First, whether the court's action in granting the motion to va-

*Honorable Ralph B. Guy, Jr., United States District Judge for the Eastern District of Michigan, sitting by designation.

cate the stipulated order prohibiting the dispensing of the drugs except by veterinarian's prescription is appealable. Second, if the order is appealable, whether the court's ruling was in error and requires reversal by this court.

The government contends that the district court's ruling is appealable under 28 U.S.C. § 1292(a)(1).¹ This section provides a right of appeal from interlocutory decisions which grant, deny, or dissolve injunctions. The record here shows that the order from which the government appeals dissolved, over the government's objection, the stipulated order which prohibited distribution of drugs except by prescription.

We conclude that the order vacating the stipulated order amounted to the dissolution or refusal of an injunction within the meaning of § 1292(a)(1). The basis for the district court's vacating of the order was its opinion that the FDA had no authority, as a proposition of law, to require that the drugs be distributed only pursuant to a prescription. Thus the injunction was dissolved or refused on the merits. *Gardner v. Westinghouse Broadcasting Co.*, 437 U.S. 478, 481, n. 7, 98 S.Ct. 2451, 2453 n. 7, 57 L.Ed.2d 364 (1978).

As we find the order is appealable, we must consider whether it was an error to vacate the order enjoining

1. § 1292. Interlocutory decisions

(a) The courts of appeals shall have jurisdiction of appeals from:

(1) Interlocutory orders of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, or of the judges thereof, granting, continuing, modifying, refusing or dissolving injunctions, or refusing to dissolve or modify injunctions, except where a direct review may be had in the Supreme Court;

Colahan from distributing the nine veterinary drugs. While a district court's refusing or dissolving of a temporary injunction can be reversed on appeal only if it is determined that the district court abused its discretion, if the district court erred as a matter of law, as the government here contends, such would be an abuse of discretion. *United States v. Beaty*, 288 F.2d 653 (6th Cir. 1961).

FDA contends that, in selling the involved drugs to dairy farmers, the drugs thereby become "misbranded" within the meaning of 21 U.S.C. § 352(f) which provides:

A drug or device shall be deemed to be misbranded—

.

(f) Unless its labeling bears (1) adequate directions for use *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

In this connection, FDA relies on 21 C.F.R. § 201.5 which provides in part:

"Adequate directions for use" means directions under which the layman can use a drug safely and for the purposes for which it is intended.

The FDA further relies on 21 C.F.R. § 201.105 which provides in part:

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and

hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the Act if all the following conditions are met:

(a) The drug is:

(1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

(2) In the possession of a licensed veterinarian for use in the course of his professional practice.

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"

(c) (1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented

FDA contends that directions cannot be written which would permit a layperson to use these drugs safely. Therefore, under 21 U.S.C. § 352(f), "adequate directions for

use" cannot be written. Thus, contends FDA, under the proviso contained in § 352(f), it may require by regulation, as it has, that such drugs are exempt and thus approved for distribution *only* if the requirements of 21 C.F.R. § 201.105 are met since professional direction, in the words of the statute, "is necessary for the protection of the public health."

Colahan contends, and the district court ruled, that FDA had no authority to issue the regulation 21 C.F.R. § 201.105. As stated in the district court's opinion vacating the stipulated order:

The above-emphasized statutory proviso allows the Secretary to act only when the condition stated in § 352(f) exists: adequate directions for use as part of the label and packaging contents are unnecessary for protection of the public health. The Secretary may not act when that condition is not evident. If adequate directions for use *are* necessary for the protection of the public health, § 352(f) does not provide the Secretary with authority to draft and adopt regulations. Additionally, even when that condition is met, the Secretary is only empowered to make *exemptions* from regulation, not enact more stringent restrictions such as § 201.105. However, it is clearly the Secretary's position that adequate directions for use *are* necessary here to protect the public health, as evidenced by the requirement of a prescription and the cautionary legend. The statute just does not provide regulatory authority for situations such as this where it is claimed that "adequate directions for use" can never be written for the protection of the general public because the drug and its side-effects are so complex that it can be dispensed properly only on the advice of a veterinarian.

We conclude that, while the language of 21 U.S.C. § 352(f) and particularly the proviso therein would suggest that the FDA could exempt a drug only when directions for use are not needed, the proviso is also subject to the interpretation argued by the government. We further conclude that the government's interpretation is the correct one. We therefore reverse the decision of the district court. The reasons for our conclusion are as follows:

First, Colahan's interpretation of the statute reaches a totally unreasonable result. His interpretation would require that the FDA either allow unrestricted over-the-counter sale of all veterinary drugs or withdraw useful drugs from the market that the FDA considers to be dangerous unless sold by prescription.

We are also persuaded by the FDA's longstanding exercise of authority to issue and enforce this regulation. FDA first promulgated the challenged regulation in 1938. This administrative interpretation over many years is entitled to great weight. *Commissioner v. First Security Bank*, 405 U.S. 394, 403, n. 16, 92 S.Ct. 1085, 1091, 31 L.Ed.2d 318 (1972). Implementation of the Act's complex statutory scheme is a job entrusted in the first instance to the FDA. Therefore, since there is more than one reasonable interpretation of this statute, the court should follow the interpretation urged by the FDA. *Udall v. Tallman*, 380 U.S. 1, 85 S.Ct. 792, 13 L.Ed.2d 616 (1965); *United States v. Articles of Drug*, 625 F.2d 665 (5th Cir. 1980).

Further supporting FDA's position is the clear indication that Congress has been aware since 1938 of the FDA's interpretation of its statutory authority while it was legislating in this area, and yet Congress has not restricted such FDA authority. Congress passed the Durham-Humphrey Amendments in 1951. 65 Stat. 648 (1951).

This amended parts of the Act's regulatory scheme. The House report noted awareness of the authority asserted by the FDA. In discussing "adequate directions for use," the report stated:

Drugs suitable for use only by or under the direction of a licensed practitioner have been exempted from the adequate directions requirement on condition that they be labeled . . . [with the prescription legend].

H.R. Rep. No. 700, 82d Cong., 1st Sess. 4 (1951).

Despite Congressional awareness of the FDA's interpretation of its authority under the Act, and despite revisions of the Act in 1951 and 1962,² Congress has not eliminated or modified FDA's asserted authority. "[A]n agency's longstanding construction of its statutory mandate is entitled to great respect, 'especially when Congress has refused to alter the administrative construction.'" *Board of Governors v. First Lincolnwood Corp.*, 439 U.S. 234, 248, 99 S.Ct. 505, 513, 58 L.Ed.2d 484 (1978). Once an agency's interpretation of a statute has been brought to the attention of Congress, and Congress has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned. *United States v. Rutherford*, 442 U.S. 544, 554, n. 10, 99 S.Ct. 2470, 2476 n. 10, 61 L.Ed.2d 68 (1979).

Lastly, this assertion of FDA authority has been recognized and approved by the courts. *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951); *United States v. Articles of Drug*, 625 F.2d 665 (5th Cir. 1980).

2. See Drug Amendments of 1962, Pub.L.No. 87-781, 76 Stat. 780 (1962); Federal Food, Drug, and Cosmetic Act Amendments (Durham-Humphrey amendments) Pub.L.No. 82-215, 65 Stat. 648 (1951).

Therefore, we conclude that the district court erred as a matter of law in dissolving the stipulated order preventing Colahan from dispensing certain veterinary drugs without prescription on the ground that FDA had no authority to require prescriptions as a prerequisite to dispensing of the drugs. We remand with instructions to the district court to reinstate the stipulated order and for further proceedings not inconsistent with this opinion.

**MEMORANDUM OPINION AND ORDER OF THE
UNITED STATES DISTRICT COURT**

(Filed October 9, 1979)

No. C 78-1470 A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA,
Plaintiff,

v.

JERRY J. COLAHAN, *et al.*,
Defendants.

MEMORANDUM OPINION AND ORDER

LAMBROS, District Judge

This action was brought by the United States under the Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* ("the Act"), to enjoin defendants (individual distributors of veterinary drugs) from selling certain prescription veterinary drugs directly to dairymen and other customers. A Temporary Restraining Order and a stipulated order were issued, based on the presumed validity of a federal regulation, 21 C.F.R. §201.105. That regulation was promulgated by the Secretary of the then Department of Health, Education and Welfare under the cited statutory authority of 21 U.S.C. §352(f). The question now before the Court is whether §201.105 is a valid and enforceable regulation. It is agreed that the Act prohibits the introduction or delivery of adulterated or mis-

branded foods, drugs, devices or cosmetics into interstate commerce, and the

“adulteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.”

21 U.S.C. §§331(a), (k). The federal regulation, 21 C.F.R. §201.105, was issued by the Secretary under the authority of 21 U.S.C. §352(f), which provides the following:

A drug or device shall be deemed to be misbranded—

* * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in the pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *PROVIDED, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.* (emphasis supplied).

Finally, the controversial regulation, §201.105, reads in part as follows:

A drug intended for veterinary use which, because of toxicity or other harmful potentiality for harmful effect, or the method of its use, is not safe for animal use

except under the supervision of a licensed veterinarian, and hence, for which "adequate directions for use" cannot be prepared, shall be exempt from [21 U.S.C. §352(f)(1)] if all the following conditions are met:

(a) The drug is . . . sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice. . . . (b) The label of the drug bears: (1) The statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and (2) The recommended or usual dosage; and (3) The route of administration, if it is not for oral use; and (4) The quantity or proportion of each active ingredient. . . .

(c) (1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contra-indications and precautions under which veterinarians . . . can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented. . . .

The above-emphasized statutory proviso allows the Secretary to act only when the condition stated in §352(f) exists: adequate directions for use as part of the label and packaging contents are unnecessary for protection of the public health. The Secretary may not act when that condition is not evident. If adequate directions for use *are* necessary for the protection of the public health, §352(f) does not provide the Secretary with authority to draft and adopt regulations. Additionally, even when that condition is met, the Secretary is only empowered to make *exemptions* from regulation, not enact more stringent restrictions such as §201.105. However, it is clearly the Secretary's

position that adequate directions for use *are* necessary here to protect the public health, as evidenced by the requirement of a prescription and the cautionary legend. The statute just does not provide regulatory authority for situations such as this where it is claimed that "adequate directions for use" can never be written for the protection of the general public because the drug and its side-effects are so complex that it can be dispensed properly only on the advice of a veterinarian. Thus the Secretary has over the years adopted the position that §352(f) gives him the inherent authority to fill the hiatus in that statute—i.e., the area where certain drugs are necessary for the public health but will always be technically misbranded because "adequate directions for use" are impossible to devise—by enacting regulations such as §201.105. But such administrative action, albeit logical, does not justify judicial addition to the language of the statute because this Court should not be required "to supply an omission in the statute or to hold that Congress must have intended to do that which it has failed to do." *United States v. Goldenberg*, 168 U.S. 95, 103 (1897).

In *United States v. Sullivan*, 332 U.S. 689 (1948), a retail druggist took several pills from a container properly labeled for human drugs and placed them in another container which was not properly labeled. The druggist then sold the pills in the new container. The Supreme Court, in a decision delivered by Justice Black, held that the acts of the druggist violated the requirements of "adequate directions for use." In so holding, the Supreme Court gave a literal construction to the Act. The pharmacist argued in opposition that such a strict ruling would apply to similar sales of foods, drugs and cosmetics. The majority noted that that conclusion would not necessarily follow, and that statement was further explained in the

concurring opinion of Justice Rutledge. In his analysis, Justice Rutledge discussed the proviso to §352(f), which of course concerns the Court today:

... The intent to protect the public health is further emphasized with the limited scope of the proviso, which directs the [Secretary] to make exemptions only when compliance with clause (1) "is not necessary for the protection of the public health." ... Under [§352 (f), the Secretary] is given no power to exempt on the ground that compliance is impracticable. He cannot weigh business convenience against protecting the public health. Only where he finds that labeling is not necessary to that protection is he authorized to create an exemption for drugs and devices. Health security is not only the first, it is the exclusive, criterion.

332 U.S. at 702-703. It is thus clear to this Court that a common sense, literal reading of §352(f) is called for, although the Court is aware that such a position may come as a shock to the FDA at this late date, especially since other courts have long since allowed the Secretary the wide latitude and discretion claimed here. See, e.g., *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62 (9th Cir. 1951).

Although administrative regulations are entitled to a presumption of validity, they can be annulled and found unenforceable when in excess of statutory authority as determined by the natural and plain meaning of the Congressional enactment. See, e.g. *Osaka Shosen Kaisha Line v. United States*, 300 U.S. 98, 101 (1937); *Western Union Tel. Co. v. F.C.C.*, 542 F.2d 346 (3rd Cir.), cert. denied, 429 U.S. 1092 (1976); *Diamond Roofing Co. v. O.S.H.R.C.*, 528 F.2d 645 (5th Cir. 1976). Despite the equities of this case and the Secretary's admirable concern for the health of

all citizens, the Court feels it is bound by that principle to reach the result found here. Finally, the Court does not view this case as one where the agency's historical interpretation of one of its enabling statutes is to be afforded considerable deference. See, e.g., *Young v. Tennessee Valley Authority*, F.2d, No. 77-1243 (6th Cir., Sept. 24, 1979). At least at this juncture, it is not clear that Congress has explicitly ratified the agency's interpretation as in *Young*. But most importantly, the statute in question in *Young* was arguably ambiguous on its face, whereas here the proviso to §352(f) speaks plainly and unequivocally. See discussion *infra*.

From the beginning of this action, the Government has relied upon §352(f) as the statutory authorization for §201.105. However, the Government has since modified its position to assert additional statutory authority under 21 U.S.C. §360b(d)(1), the New Animal Drug Amendment, as well as 21 U.S.C. §371(a). To begin with, §360b was not enacted until 1968, whereas the key language of §201.105 was promulgated years earlier. Therefore, §360b cannot have been the statutory basis for §201.105. Whether the Secretary could in the future require a prescription and cautionary legend under §360b is an entirely different issue than the one presently before the Court; application of §360b to the facts here is still an undetermined question, and further consideration may well result in an alternative basis for liability. The primary question at this time is still whether the §201.105 stood upon firm statutory footing when promulgated.

Second, §371(a) provides as follows:

The authority to promulgate regulations for the efficient enforcement of this chapter; except as otherwise provided in this section, is vested in the Secretary.

The authority of the Secretary to make binding regulations under §371(a) is not challenged. Surely, such a challenge would be fruitless, as demonstrated by the Second Circuit in *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688, 696-697 (2nd Cir.), *cert. denied*, 423 U.S. 823 (1975):

Whatever doubts might have been entertained regarding the FDA's power under [§371(a)] to promulgate binding regulations were dispelled by the Supreme Court's recent decision in *Weinberger v. Hyson, Westcott & Dunning, nc.*, 412 U.S. 609, 93 S. Ct. 2469, 37 L.Ed. 2d. 207 (1973), and its companion cases, *Ciba Corp. v. Weinberger*, 412 U.S. 640, 93 S. Ct. 2495, 37 L.Ed. 2d. 230 (1973); *Weinberger v. Bentex Pharamaceuticals, Inc.*, 412 U.S. 645, 93 S.Ct. 2488, 37 L.Ed. 2d. 235 (1973); *U.S.V. Pharmaceutical Corp. v. Weinberger*, 412 U.S. 655, 93 S.Ct. 2498, 37 L.Ed. 2d. 244 (1973). Those decisions interpreted [§371(a)] as giving FDA the power to promulgate substantive regulations having the binding force of law rather than mere "interpretive" standards enforceable only on a case-by-case basis through plenary suits against those refusing to comply. -

However, what is challenged here is whether §201.105 was properly promulgated in the first place, and hence entitled to the binding effect afforded by §371(a). The Government asserts that FDA interpretations of §371(a) and the regulation cloaks §201.105 with an authoritative blanket. However, the rule that agency construction of its own regulations is entitled to great weight only applies where the relevant statutory language is unclear or susceptible to differing interpretations. See *Young v. Tennessee Valley Authority*, *supra*; *Air Transport authority Association of America v. Brownell*, 124 F.Supp. 909 (D.D.C. 1954). Thus,

where the language of a statute is clear on its face, a court cannot avoid its duty of so construing the statute by deferring to a prior, contrary agency interpretation. *Aviation Consumer Action Project v. C.A.B.*, 412 F.Supp. 1028 (D.C. 1976), *motion granted in part, denied in part*, 418 F.Supp. 634 (1976). Furthermore, agency decisions which rest on an erroneous legal foundation, or which are inconsistent with a statutory mandate, should be struck down, *N.L.R.B. v. Brown*, 380 U.S. 278, 291-292 (1965), and are not persuasive in judicial proceedings. *Florida Citrus Exchange v. Folsom*, 246 F.2d 850 (5th Cir. 1957), *reversed on other grounds*, 358 U.S. 153, *reh. denied*, 358 U.S. 948 (1958).

The Government asserts that the Secretary relied on §371(a) in enacting §1.106, now §201.105, as evidenced by Exhibit A attached to its Third Memorandum. Section 371(a) is a general grant of authority to enact regulations for the limited purpose of efficient enforcement of the Act. Accordingly, a regulation exempting veterinary drugs from providing adequate directions for use must necessarily be consistent with the Congressional mandate of §352(f) that exemptions from such regulation be limited to the circumstances stated therein. Thus the regulation, being in excess of the narrow authority granted by §352(f), could not properly be found valid under the general grant of authority in §371(a). The regulation could not have been promulgated for the "efficient enforcement" of the Act when the Act specifically limits such regulation in §352(f). As with the direct analysis under §352(f), the Secretary has also gone beyond the broader, but still limited grant of authority of §371(a). It is not the function of the courts to vindicate the wisdom of the law, *Merchants' Insurance Company v. Ritchie*, 5 Wall 541, 18 L.Ed. 540, 544, 545 (1867), but rather it is the duty of the Court to interpret

a statute as it finds it, without reference to whether its provisions are wise or unwise. *United States v. South-Eastern Underwriters Association*, 322 U.S. 533, 561 (1943); *Olsen v. Nebraska*, 313 U.S. 236, 247 (1940). Finally, the Secretary has amended the complaint to allege (1) adulteration of drugs and (2) improper application for permission to sell new animal drugs under 21 U.S.C. §360b. While the government legitimately may be able to proceed against the defendants for the relief it seeks under those amendments, the Temporary Restraining Order and the stipulated order were not entered on the basis of either of those legal theories. Hence the Court chooses not to address them.

In light of the above discussion the Court finds that there is considerable doubt at this stage whether plaintiff would prevail on the merits, and thus the Temporary Restraining Order and the accompanying stipulated order must be vacated. Rule 65(b), Fed. R. Civ.P. That is not to say, however, that further proceedings will not vindicate the Secretary's position and ultimately entitle plaintiff to the relief sought. Accordingly, the Court cautions against incorrect interpretation of this order. The Court does not hold that the Secretary cannot protect the public health. The Court does not hold that defendants did not violate the Act and that defendants cannot at some point be prevented from selling dangerous drugs which humans may indirectly consume. Those issues have yet to be decided. Rather, the Court holds only that these defendants cannot be enjoined at this time from the conduct complained of under the authority of §201.105.

A pretrial conference with the Court is scheduled for November 15, 1979 at 1:30 p.m.

IT IS SO ORDERED. _____

/s/ THOMAS D. LAMBROS

United States District Judge

21 U.S.C. § 321(w)

§ 321. Definitions; generally

For the purposes of this chapter—

(w) The term “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a “new animal drug” if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new

animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

21 U.S.C. § 331(a-d)

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

* * * * *

21 U.S.C. § 332(a-b)

§ 332. Injunction proceedings—Jurisdiction of courts.

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdic-

tion, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (h)-(j) of said section.

Violation of injunction

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of Title 28.

21 U.S.C. § 352(f)

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

* * * * *

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 U.S.C. § 360b

§ 360b. New animal drugs—Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research

(a) (1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a) (5) and section 342(a)-(2) (D) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug.

(B) such drug, its labeling, and such use conform to such approved application, and

(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) is in effect with respect to such drug.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee—

(i) is the holder of an approved application under subsection (m) of this section; or

(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 351(a) (6) of this title unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m) (1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a) (5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

Filing application for uses of new animal drug; contents

(b) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or

not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (7) a description of practicable methods for determining the quantity, if any, of such drug in or-on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

**Period for approval of application; period for, notice,
and expedition of hearing; period for issuance
of order**

(c) Within one hundred and eighty days after the filing of an application pursuant to subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (1) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or (2)

give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for a hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

**Withdrawal of approval; grounds; immediate
suspension upon finding imminent hazard to
health of man or animals**

(e) (1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds—

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved;

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the condi-

tions of use upon the basis of which the application was approved or that subparagraph (H) of paragraph (1) of subsection (d) of this section applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) that the application contains any untrue statement of a material fact; or

(E) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds—

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (1) of this section, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

Service of orders

(g) Orders of the Secretary issued under this section (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

Appeal from order

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 355 of this title shall govern any such appeal.

Publication in Federal Register; effective date and revocation or suspension of regulation

(i) When a new animal drug application filed pursuant to subsection (b) of this section is approved, the Secretary shall be notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval

of such new animal drug application or upon its suspension, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i) insofar as it is based on the approval of such application.

21 C.F.R. § 201.105 (1986)

§ 201.105 Veterinary drugs.

A drug intended for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is:

(1) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice; or

(2) In the possession of a licensed veterinarian for use in the course of his professional practice.

(b) The label of the drug bears:

(1) The statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; and

(2) The recommended or usual dosage; and

(3) The route of administration, if it is not for oral use; and

(4) The quantity or proportion of each active ingredient as well as the information required by section 502(e) of the act; and

(5) If it is for other than oral use, the names of all inactive ingredients, except that:

(i) Flavorings and perfumes may be designated as such without naming their components.

(ii) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in Subchapter A of this chapter.

(iii) Trace amounts of harmless substances added solely for individual product identification need not be named.

If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection, it need not be named.

(6) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug;

Provided, however, That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by paragraphs (b) (2), (3), and (5) of this section may be contained in other labeling on or within the package from which it is to be so dispensed, and the information referred to in paragraph (b) (1) of this section may be placed on

such outer container only, and the information required by paragraph (b)(6) of this section may be on the crimp of the dispensing tube.

(c)(1) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and

(2) If the article is subject to section 512 of the act, the labeling bearing such information is the labeling authorized by the approved new animal drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of antibiotic drugs: *Provided, however,* That the information required by paragraph (c)(1) of this section may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to veterinarians licensed by law to administer the drug. Upon written request, stating reasonable grounds therefore, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(d) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information, or suggests a dosage for the use of the drug (other than dose information required by paragraph (b)(2) of this section and § 201.100(b)(2)) contains:

(1) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant warnings, hazards, contraindications, side effects, and precautions, and including information relevant to compliance with the new animal drug provisions of the act, under which veterinarians licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 512 of the act, the parts of the labeling providing such information are the same in language and emphasis as labeling approved or permitted under the provisions of section 512, and any other parts of the labeling are consistent with and not contrary to such approved or permitted labeling; and

(2) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed; *Provided, however,* That the information required by paragraphs (d) (1) and (2) of this section is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does not include indications or dosage recommendations for use of the drug.

(e) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the last revision of such labeling.

(f) A prescription drug intended for both human and veterinary use shall comply with paragraphs (e) and (f) of this section and § 201.100.

[40 FR 13998, Mar. 27, 1975, as amended at 42 FR 15674, Mar. 22 1977]

(3)
No. 86-1783

Supreme Court, U.S.
FILED

JUL 11 1987

JOSEPH E. SPANIOL, JR.
CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1987

JERRY J. COLAHAN, d/b/a
IBA OF OHIO, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Federal Food, Drug, and Cosmetic Act permits a defendant to challenge in an enforcement proceeding the prescription status of a drug which has been determined by the Food and Drug Administration in the course of the approval of a new animal drug application.

2. Whether the forms used by petitioners for the distribution of new animal drugs satisfied the requirement that the drugs be sold "only to or on the prescription or other order of a licensed veterinarian" (21 C.F.R. 201.105(a)(1)).



TABLE OF CONTENTS

| | Page |
|----------------------|------|
| Opinions below | 1 |
| Jurisdiction | 1 |
| Statement | 2 |
| Argument | 8 |
| Conclusion | 14 |

TABLE OF AUTHORITIES

Cases:

| | |
|---|----------|
| <i>American Cyanamid Co. v. Young</i> , 770 F.2d 1213 (D.C. Cir. 1985) | 3, 10 |
| <i>Bradley v. Weinberger</i> , 483 F.2d 410 (1st Cir. 1973) | 3 |
| <i>Ciba Corp. v. Weinberger</i> , 412 U.S. 640 (1973) | 9, 12 |
| <i>Edison Pharmaceutical Co. v. FDA</i> , 600 F.2d 831 (D.C. Cir. 1979) | 3 |
| <i>Ewing v. Mytinger & Casselberry, Inc.</i> , 339 U.S. 594 (1950) | 12 |
| <i>Luckhard v. Reed</i> , No. 85-1358 (Apr. 22, 1987) | 13 |
| <i>Lyng v. Payne</i> , No. 84-1948 (June 7, 1986) | 13 |
| <i>Premo Pharmaceutical Laboratories, Inc. v. United States</i> , 629 F.2d 795 (2d Cir. 1980) | 9-10, 12 |
| <i>Rutherford v. United States</i> , 806 F.2d 1455 (10th Cir. 1986) | 9 |
| <i>United States v. An Article of Drug Consisting of 4,680 Pails (Neo-Terra)</i> , 725 F.2d 976 (5th Cir. 1984) | 2, 9, 10 |
| <i>United States v. Article of Device</i> , 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984) | 12-13 |
| <i>United States v. Articles of Drug</i> , 585 F.2d 575 (3d Cir. 1978) | 12 |
| <i>United States v. Generix Drug Corp.</i> , 460 U.S. 453 (1983) | 2 |
| <i>United States v. Undetermined Quantities of Vari- ous Articles of Drug</i> , 675 F.2d 994 (8th Cir. 1982), cert. denied, 460 U.S. 1051 (1983) | 9 |
| <i>United States v. X-Otag Plus Tablets</i> , 602 F.2d 1387 (10th Cir. 1979) | 12 |

IV

Cases—Continued:

Page

| | |
|--|-------------|
| <i>Weinberger v. Hynson, Westcott & Dunning, Inc.</i> , 412 U.S. 609 (1973) | 2, 3, 9, 11 |
| <i>Whitney Nat'l Bank v. Bank of New Orleans & Trust Co.</i> , 379 U.S. 411 (1965) | 9 |

Statute and regulations:

| | |
|---|--------------|
| Federal Food, Drug, and Cosmetic Act, 21 U.S.C. (& Supp. III) 301 <i>et seq.</i> | 2 |
| § 201 (g), 21 U.S.C. 321 (g) | 2 |
| § 201 (w), 21 U.S.C. 321 (w) | 2, 9, 10, 12 |
| § 301, 21 U.S.C. 331 | 5, 6 |
| § 301 (a), 21 U.S.C. 331 (a) | 4, 6 |
| § 301 (k), 21 U.S.C. 331 (k) | 6 |
| § 502, 21 U.S.C. 352 | 6 |
| § 502 (f), 21 U.S.C. 352 (f) | 4, 8, 12 |
| § 505 (a), 21 U.S.C. 355 (a) | 2 |
| § 505 (h), 21 U.S.C. 355 (h) | 3, 9 |
| § 510 (h), 21 U.S.C. 360 (h) | 3 |
| § 512, 21 U.S.C. 360b | 4 |
| § 512 (a) (1) (A), 21 U.S.C. 360b (a) (1) (A) | 2 |
| § 512 (c), 21 U.S.C. 360b (c) | 3 |
| § 512 (e) (1) (E), 21 U.S.C. 360b (e) (1) (E) | 10 |
| § 512 (h), 21 U.S.C. 360b (h) | 3, 9 |
| § 512 (i), 21 U.S.C. 360b (i) | 3 |
| § 512 (m) (4) (A) (ii), 21 U.S.C. 360b (m) (4) (A) (ii) | 10 |
| 21 C.F.R.: | |
| Pt. 10: | |
| Section 10.25 | 11 |
| Section 10.45 (d) | 11 |
| Pt. 201: | |
| Section 201.5 | 4 |
| Section 201.105 | 6, 8, 13 |
| Section 201.105 (a) (1) | 5 |
| Section 201.105 (b) (1) | 5 |
| Pt. 514: | |
| Section 514.1 (a) | 4 |
| Section 514.11 (b) | 2 |
| Pts. 529-555 | 3 |
| Pt. 558 | 3 |

In the Supreme Court of the United States

OCTOBER TERM, 1987

No. 86-1783

JERRY J. COLAHAN, d/b/a
IBA OF OHIO, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT*

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A23) is reported at 811 F.2d 287. The memorandum opinion and order of the district court (Pet. App. A29-A48) is unreported. An earlier opinion of the court of appeals (Pet. App. A49-A57) is reported at 635 F.2d 564. An earlier memorandum opinion and order of the district court (Pet. App. A58-A66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 5, 1987. The petition for writ of certiorari was filed on May 5, 1987. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. (& Supp. III) 301 *et seq.*, established a system of premarketing approval for new human and animal drugs.¹ 21 U.S.C. 355(a), 360b(a)(1)(A); see *United States v. Generix Drug Corp.*, 460 U.S. 453, 458 (1983); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612 (1973); *United States v. An Article of Drug Consisting of 4,680 Pails (Neo-Terra)*, 725 F.2d 976, 978 (5th Cir. 1984). The Act prohibits the introduction of a new animal drug into interstate commerce unless the Food and Drug Administration (FDA) has approved a new animal drug application (NADA) for it. 21 U.S.C. 360b(a)(1)(A); *Neo-Terra*, 725 F.2d at 980. The NADA approval process is an adjudication in which the FDA decides whether to grant a license to the sponsor² and under what conditions

¹ Section 201(g) of the Act defines "drugs" to include both human and veterinary drugs. 21 U.S.C. 321(g). A drug is a "new drug" or a "new animal drug" unless it is generally recognized by experts as safe and effective for its intended uses. See 21 U.S.C. 321(w); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973); *United States v. An Article of Drug Consisting of 4,680 Pails (Neo-Terra)*, 725 F.2d 976, 980 (5th Cir. 1984).

² NADA approvals are not generic, and the FDA's decision whether to approve a drug is not a public proceeding. Rather, the agency decides on the basis of the specific facts submitted by the sponsor whether a particular application should be approved. The pendency of an NADA is confidential, and ordinarily does not become public knowledge until the FDA approves an application and publishes the approval regulation. 21 C.F.R. 514.11(b). If the agency issues an order refusing to approve an application, only the applicant may appeal, even though the existence of the NADA becomes public

the drug will be approved (*e.g.*, whether it may be dispensed only by prescription or may be sold over-the-counter). The FDA has exclusive jurisdiction to approve or disapprove a NADA, and to impose conditions under which an approved drug may be used, which are specified in the drug's labeling. See, *e.g.*, 21 U.S.C. 360b(i); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 627.³ If the FDA rejects a NADA because, for example, one of the proposed conditions of use (such as over-the-counter use) is unacceptable to the agency, the drug sponsor can seek an administrative hearing. 21 U.S.C. 360b (c). If the hearing proves unsuccessful, the sponsor can seek judicial review of the agency's decision in the court of appeals, but the agency's decision must be upheld if it is supported by substantial evidence. 21 U.S.C. 360b(h), incorporating 21 U.S.C. 355(h); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 625-626; *American Cyanamid Co. v. Young*, 770 F.2d 1213, 1218, 1220 (D.C. Cir. 1985); *Edison Pharmaceutical Co. v. FDA*, 600 F.2d 831 (D.C. Cir. 1979). No other firm may market a sim-

at that time. 21 U.S.C. 360(h), incorporating 21 U.S.C. 355(h); *Bradley v. Weinberger*, 483 F.2d 410, 413 n.1 (1st Cir. 1973). Thus, if the agency refuses to approve an original or a supplemental application requesting over-the-counter sale of an approved prescription drug, only the sponsor can appeal the decision.

³ When it approves a veterinary drug, FDA is required, by 21 U.S.C. 360b(i), to publish a regulation that lists, among other things, the drug's conditions of use. See 21 C.F.R. Pts. 529-555 and 558. Not all of the approvals of the fifteen drugs in issue here are so listed, because 21 U.S.C. 360b(i) did not become effective until 1969, after some of the approvals had been granted. Some, but not all, of the pre-1969 approvals have since been listed.

ilar drug without a separate approval, and no other firm may rely in support of an application upon the data submitted by a prior sponsor. 21 C.F.R. 514.1(a).

The FDCA also prohibits any person from introducing into interstate commerce any human or veterinary drug that is "misbranded." 21 U.S.C. 331(a). To avoid being deemed misbranded, Section 502(f) of the FDCA, 21 U.S.C. 352(f), requires that drugs bear "adequate directions for use," which means adequate directions for use by laymen. 21 C.F.R. 201.5. A proviso to Section 502(f), however, authorizes the FDA to exempt drugs from the requirement that a drug bear adequate directions for use where it "is not necessary for the protection of the public health."

Since 1938, the FDA has recognized that some animal drugs cannot be used safely except under a veterinarian's supervision, and that such drugs, by definition, cannot be labeled adequately for laymen's use. Such drugs nonetheless can be of great medical benefit when used under the direction of a licensed health professional. Thus, rather than ban the drugs as misbranded, the FDA has exempted them under the proviso to Section 502(f) so long as they are sold pursuant to a veterinarian's prescription or other order. The agency's rationale is that "adequate directions for use" are not "necessary" because the veterinarian's directions protect the public health. The result of this policy is that many useful veterinary drugs are now available which otherwise would have to be withdrawn.⁴

⁴ Nearly half of the roughly 1200 veterinary drugs for which the agency has approved New Animal Drug Applications (see 21 U.S.C. 360b) are labeled for use only by or on

Current FDA regulations specify essentially three relevant conditions for an exemption. First, the drugs must be distributed by persons who are "regularly and lawfully engaged in" the handling of such drugs. 21 C.F.R. 201.105(a)(1). Second, the drugs must be "sold only to or on the * * * order of" a licensed practitioner for use in his professional practice (*ibid.*). And third, the drugs must bear, *inter alia*, a legend stating: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 21 C.F.R. 201.105(b)(1). Veterinary drugs which can be used properly only under the supervision of a veterinarian, but which do not satisfy all three conditions for an exemption, are misbranded, because they do not and cannot bear adequate directions for lay use.

2. On November 3, 1978, the government brought suit in the United States District Court for the Northern District of Ohio, seeking to enjoin petitioner Colahan and his dealers⁵ from the distribution of various veterinary prescription drugs without a prescription or other veterinarian's order, in violation of Section 301 of the FDCA, 21 U.S.C. 331 (Pet. App.

the order of a veterinarian. Included are narcotics, barbiturates, anesthetics, anticonvulsants, hormones (including steroids), stimulants, and tranquilizers.

⁵ Petitioners IBA, Inc., a Massachusetts corporation, and Daniel J. Belsito, President of IBA, market veterinary prescription drugs through franchised distributors located across the United States. These distributors, in turn, sell the drugs to IBA dealers (route salesmen), who retail the drugs. Most of the IBA customers are dairymen and other farmers. Petitioner Jerry J. Colahan, doing business as IBA of Ohio, is the IBA distributor in Ohio. His co-petitioners are IBA dealers who receive their drugs from him.

A2).⁶ All but two of the drugs had been approved by the FDA through action on a NADA that had been submitted by the drug's manufacturer. On November 3, 1978, the district court entered a temporary restraining order prohibiting petitioners from distributing misbranded drugs. Shortly thereafter, the court entered a stipulated order pursuant to which the defendants agreed not to distribute nine named drugs except on a veterinarian's prescription until further order by the court. *Id.* at A3, A27.⁷

On October 9, 1979, the district court held that FDA lacked statutory authority to promulgate 21 C.F.R. 201.105, under which FDA regulated veterinary prescription drugs, and the court dissolved the stipulated order (Pet. App. A58-A66). The government appealed, and the court of appeals reversed the district court's ruling, concluding that FDA possessed the statutory authority to restrict certain veterinary drugs to use by or on the prescription or other order of a veterinarian (*id.* at A49-A57; 635 F.2d 564). This Court denied certiorari. 454 U.S. 831 (1981).

3. On remand, the district court ruled that petitioners had violated 21 U.S.C. 331 and 352, and 21 C.F.R. 201.105, by engaging in the retail distribution

⁶ Section 301(a) of the Act, 21 U.S.C. 331(a), prohibits the introduction or delivery for introduction into interstate commerce of any misbranded drug. Section 301(k), 21 U.S.C. 331(k), prohibits the doing of any act to any drug while held for sale after shipment in interstate commerce which results in the drug's being misbranded.

⁷ On August 16, 1979, the government brought a separate action against petitioner IBA in the United States District Court for the District of Massachusetts. That case was ultimately transferred to the Northern District of Ohio and was consolidated with the earlier action. Pet. App. A35.

7

of misbranded veterinary drugs (Pet. App. A29-A48). At the outset, the court noted that the FDA had approved 14 of the drugs at issue as new animal drugs⁸ and had required a cautionary prescription legend as a condition of its approval (*id.* at A33). The court ruled that FDA has primary jurisdiction to make such determinations and that a district court could not review the agency's decision regarding the prescription status of the drugs (*id.* at A37-A39). The district court explained that Congress granted the FDA primary jurisdiction over the determination whether to approve the interstate distribution of new animal drugs, and that allowing parties such as petitioners to challenge the FDA's determination of the prescription status of the drugs would be inconsistent with the congressional scheme (*id.* at A37-A38).⁹

⁸ The 14 new animal drugs are listed at Pet. App. A6 n.2 & A29-A30. The district court's ruling also included a fifteenth such drug, but the court later excluded that drug from the scope of its injunction on a stipulation by the parties that the drug could be purchased over the counter without a prescription (*id.* at A27-A28).

⁹ The court added that a district court may determine whether a caution legend is unnecessary when the FDA has not considered the question whether a given drug is a new animal drug (Pet. App. A38). In that circumstance, however, a district court could determine only whether there is a general recognition among experts that a given drug is safe and effective, rather than whether the drug is in fact safe and effective, for example, for over-the-counter sale, which is for the agency to determine in the NADA process (*id.* at A38-A39). In this case, the FDA had previously considered the question whether 14 of the products at issue were "new animal drugs," since the agency had approved NADAs for them.

With regard to two drugs not previously approved by the FDA, the court held that one drug could not be dispensed without a prescription above a particular unit dosage, and

Moreover, the court concluded that a drug which can be dispensed only by prescription cannot bear "adequate directions for [lay] use" within the meaning of 21 U.S.C. 352(f) (Pet. App. A40-A41). Finally, the district court found that the "slip system" used by petitioners did not amount to a "prescription or other order of a licensed veterinarian" within the meaning of 21 C.F.R. 201.105 (Pet. App. A41-A43).¹⁰ Petitioners' order forms were inadequate, the court found, because they did not require that a veterinarian authorize the distribution of a prescription drug (*id.* at A42-A43).

4. The court of appeals affirmed the district court in all respects (Pet. App. A1-A23). The court held that the government is entitled to rely on the determination in the premarketing, NADA approval process that a drug cannot be safely distributed without a veterinarian's prescription (*id.* at A10-A13). The court also held that petitioner's distribution system did not comply with 21 C.F.R. 201.105 (Pet. App. A14-A16).

ARGUMENT

The court of appeals' decision is correct and does not conflict with any decision of this Court or of any other court of appeals. Accordingly, review by this Court is not warranted.

1. Petitioners contend that they are entitled to challenge the FDA's administrative determination

the other drug could not be dispensed at all without a prescription (Pet. App. A44-A47). The court of appeals affirmed that ruling (*id.* at A13), and petitioners have not challenged it in this Court (see Pet. I).

¹⁰ A copy of the "slips" used by petitioners is reprinted in the district court's opinion at Pet. App. A42.

made in the new animal drug application (NADA) process that the drugs at issue may not be distributed in interstate commerce without a prescription from a licensed veterinarian. That contention lacks merit, for several reasons.

First, when Congress has provided an agency with primary jurisdiction over a matter within its expertise, a party may not circumvent the administrative process by seeking to overturn the agency's action in district court. See, e.g., *Whitney Nat'l Bank v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 421-422 (1965). The FDA has the exclusive jurisdiction whether to approve a NADA and under what conditions a new animal drug may be used—i.e., to determine whether and under what conditions a drug is safe and effective for each of its intended uses. The FDA's determination is subject to review in the court of appeals, but its decision must be upheld if it is supported by substantial evidence. See 21 U.S.C. 355(h), 360b(h); *Ciba Corp. v. Weinberger*, 412 U.S. 640, 643-644 (1973); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 626; *Rutherford v. United States*, 806 F.2d 1455, 1461 (10th Cir. 1986); *Neo-Terra*, 725 F.2d at 978-981; *United States v. Undetermined Quantities of Various Articles of Drug*, 675 F.2d 994, 1000 (8th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795, 801-804 (2d Cir. 1980).¹¹ Moreover, the FDA

¹¹ By contrast, the district courts share with the FDA the jurisdiction to determine whether a drug is in fact a "new animal drug" subject to the FDCA if the FDA brings an enforcement action against an unapproved drug. 21 U.S.C. 321(w); *Neo-Terra*, 725 F.2d at 980-981; *Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d 795, 801

has the exclusive authority to modify the conditions of use specified in a NADA, subject to review in the court of appeals under a substantial evidence standard. See 21 U.S.C. 360b(e)(1)(E), 360b(m)(4)(A)(ii); *American Cyanamid*, 770 F.2d at 1216-1218.¹² Put another way, the FDA has the exclusive authority to determine whether a drug can be sold over-the-counter or only by prescription, and whether to modify that decision. The district court therefore lacks the authority to undertake the inquiry proposed by petitioners.

Petitioners' proposed interpretation of the Act would lead to serious disruption of the regulatory scheme. Drug manufacturers have two alternative routes to market animal drugs: they can seek FDA approval of the drug, or they can market the drug without FDA approval on the assumption that the product is not a "new animal drug" subject to the FDCA. *E.g.*, *Neo-Terra*, 725 F.2d at 981. Petitioners' construction of the Act would provide the distributors of a drug with greater rights than the drug's manufacturers, because under petitioners' interpretation, distributors could at any time obtain de novo review in district court of the FDA's determination regarding the prescription status of a drug,

(2d Cir. 1980). In that case, however, the question before the district court is not whether the drug in fact is safe and effective for each of its intended uses, but is whether the drug is "generally recognized" by qualified experts as safe and effective for each such use. 21 U.S.C. 321(w); *Neo-Terra*, 725 F.2d at 980-981.

¹² A change in the conditions of use, including a change in the marketing status of an approved drug, is accomplished by FDA action on a supplemental NADA. 21 U.S.C. 306b(e)(1)(E).

even though the sponsors of that drug are limited to seeking timely review in the courts of appeals under a more restricted standard of review. Alternatively, petitioners' construction of the Act would allow the sponsors of a drug to obtain de novo review in district court of the FDA's prescription status decision simply by refusing to market the drug under the conditions approved by the FDA. Moreover, permitting the marketing status (*i.e.*, prescription or over-the-counter status) of a drug to be challenged in an enforcement action in district court would also create considerable uncertainty as different courts resolved this question in a different manner. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 626 (“[o]nly paralysis would result if case-by-case battles in the courts were the only way to protect the public against unsafe or ineffective drugs”). Finally, allowing such challenges would enable parties such as petitioners to challenge a condition on the use of a drug in an action in which the drug's sponsor is not a participant.

Contrary to petitioners' suggestion (Pet. 11-12), the court of appeals did not at all rely on collateral estoppel principles as a basis for its decision. Petitioners also erroneously assert (Pet. 11) that they have no opportunity to participate in the administrative process by which drugs are approved as prescription drugs. Parties such as petitioners, who disagree with a drug's prescription status, can file a citizens petition with the FDA seeking an amendment to the order approving a NADA. See 21 C.F.R. 10.25. If the FDA declines to amend its order, the agency's decision is subject to judicial review. See 21 C.F.R. 10.45(d). Petitioners can also encourage the sponsors of the drugs they wish to distribute to submit a

supplemental application to the agency seeking a change in the marketing status of the drugs. All that the court of appeals has held is that petitioners cannot circumvent the system devised by Congress and implemented by FDA by challenging the prescription status of drugs in an enforcement action.

The court of appeals' decision does not conflict with any of the decisions cited by petitioners. *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), held only that a district court lacks jurisdiction to enjoin multiple seizures in actions brought by the FDA under the Act. *Ciba Corp. v. Weinberger*, held that a drug's sponsor may not challenge in district court the FDA's determination in the NADA process that the drug is a new drug subject to the FDCA (412 U.S. at 643-644). Finally, none of the lower court decisions cited by petitioners ruled that a district court has jurisdiction to determine whether a new animal drug is safe and effective for its intended use, or to approve a change in the conditions under which the FDA has approved the use of a drug. Rather, those decisions simply recognize that a district court has concurrent jurisdiction with the FDA to determine whether a product is a "new drug"—i.e., whether it is "generally recognized" as safe and effective (21 U.S.C. 321(w))—only if the agency has not already made that determination. See *Ciba Corp. v. Weinberger*, 412 U.S. at 643-644.¹³ In this case, how-

¹³ See *Premo Pharmaceutical Laboratories, Inc. v. United States*, 629 F.2d at 801-805; *United States v. X-Otag Plus Tablets*, 602 F.2d 1387 10th Cir. 1979); *United States v. Articles of Drug*, 585 F.2d 575, 582-583 (3d Cir. 1978). The only other circuit case cited by petitioners involved an unapproved product, a device, which the court found to be misbranded under 21 U.S.C. 352(f), rather than a drug. *United*

ever, both the new animal drug status and the conditions of approval have previously been decided by the FDA. None of the decisions cited by petitioner suggests that a district court may reconsider the FDA's determinations.

2. Petitioners refer in their questions presented (Pet. I) to the court of appeals' ruling that their sales practices violated 21 C.F.R. 201.105, but petitioners do not develop that argument in their petition. In any event, that factbound question does not warrant further review. The FDA's interpretation of its own regulations is entitled to considerable deference from the courts (*e.g.*, *Luckhard v. Reed*, No. 85-1358 (Apr. 22, 1987), slip op. 9, 12 (plurality opinion); *Lyng v. Payne*, No. 84-1948 (June 7, 1986), slip op. 12-13), and, as the courts below explained (Pet. App. A14-A16, A42-A43), the agency's interpretation is eminently reasonable. The agency's regulation is designed to ensure that prescription animal drugs will be dispensed only at the direction of a licensed veterinarian, and petitioners' order forms (see Pet. App. A42 (reprinting form)) do not provide assurance that drugs will be dispensed only in those circumstances.

States v. Article of Device, 731 F.2d 1253 (7th Cir.), cert. denied, 469 U.S. 882 (1984).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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In the Supreme Court of the United States

October Term, 1986

JERRY J. COLAHAN, d/b/a IBA OF OHIO, NORMAN F.
BAUER, JOHN D. BURROWS, RUSSELL C. HUMPHREY,
JR., SIMON E. MILLER, IBA, INC., DANIEL BELSITO,
Petitioners,

vs.

UNITED STATES OF AMERICA,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PETITIONERS' REPLY BRIEF

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TABLE OF CONTENTS

| | |
|--------------------------------|---|
| Petitioners' Reply Brief | 1 |
| Conclusion | 7 |

TABLE OF AUTHORITIES

Cases

| | |
|---|---|
| <i>Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation</i> , 402 U.S. 319 (1971) | 5 |
| <i>United States v. Utah Construction & Mining Co.</i> , 384 U.S. 394 (1966) | 5 |

Statutes

| | |
|---|---------|
| 21 C.F.R. § 201.105 | 2, 3 |
| Federal Food, Drug & Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. §§ 321-360 | |
| § 502(f), 21 U.S.C. § 352(f) | 2, 3 |
| § 503(b), 21 U.S.C. § 353 | 1, 2, 3 |

Other

| | |
|---|---|
| <i>Classification of OTC and Rx Drugs</i> , CVM Staff Manual Guide No. 1240.2220 | 3 |
| Senate Report No. 946, 82nd Cong., 1st Sess. 8 (1951) | 2 |



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PETITIONERS' REPLY BRIEF

Typical of the bootstrap argument the Government has pursued throughout this action is the sentence on page 4 of its Opposing Brief:

Since 1938, the FDA has recognized that some animal drugs cannot be used safely except under a veterinarian's supervision, and that such drugs, by definition, cannot be labeled adequately for laymen's use.

No citation is given for that statement. In 1938, Section 503(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) did recognize the possibility of "prescription"

veterinary drugs; that is, veterinary drugs for which adequate directions for lay use cannot be written. However, that section was replaced with a new Section 503(b) as part of the Durham-Humphrey Amendments of 1951. The new language limited the prescription drug category to human drugs. As stated in Senate Report No. 946, 82nd Cong., 1st Sess. 8 (1951):

In limiting prescription drugs to those intended for use by man this new subsection differs from the present law, which refers to prescription drugs to include not only those dispensed on prescription of physicians and dentists, but also those dispensed on prescription of a veterinarian. Under the committee bill, drugs intended for use under the supervision of a veterinarian will not require a prescription, although it will be possible under Section 502(f) to exempt such drugs from adequate directions for use if they are to be used by or under the supervision of a veterinarian.

Section 502(f), 21 U.S.C. § 352(f) (Appendix "App." at A69), states that a veterinary drug is misbranded *unless* its labeling bears adequate directions for use. It includes a proviso that the FDA may promulgate regulations exempting drugs from adequate labeling if such labeling "is not necessary for the protection of the public health." In 1975, the FDA promulgated 21 C.F.R. § 201.105, which seeks to establish a prescription category for veterinary drugs that:

. . . because of toxicity or other potentiality for harmful effect . . . is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared. . . .

App. at A77.

Faced, however, with the explicit language of Section 502(f) of the FDCA, the FDA historically recognized that any person charged with misbranding a veterinary drug on the basis of sale without a prescription could defend against the charge by proving that the drug contained adequate directions for lay use. *See, e.g., Classification of OTC and Rx Drugs*, CVM Staff Manual Guide No. 1240.2220; FDA's Brief in Opposition to Petition to this Court in the prior appeal of this case, Case No. 80-2067, p. 13, n.11. That was the only reasonable interpretation of Section 502(f), since that section limits the FDA's authority to promulgate regulations to veterinary drugs which do not require adequate directions for lay use. Further, 502(f) states that only drugs without adequate directions for lay use can be misbranded.

In this case, however, the FDA has done a turnaround, now claiming that 21 C.F.R. § 201.105 does obliterate the statutory defense of adequate directions for lay use. Specifically, as noted above, the FDA now claims that any veterinary drug which carries a prescription label is a toxic, unsafe drug for which adequate directions cannot be written.

The implicit assumption in the FDA's argument is that some adjudication occurs at some point during which competent authorities determine that adequate directions for lay use cannot be written for a particular veterinary drug and it is toxic and unsafe. The undisputed evidence is that no such adjudication is part of the approval process. The lack of any requirement that the veterinary drug be *found* to be unsafe without a prescription label precludes collateral use of the label alone to bar all of IBA's defenses. As summarized by Judge Jones in his dissent in the Court of Appeals:

Essentially the Government's position is that by virtue of bearing the cautionary label for New Animal Drug purposes these compounds have achieved the status of "prescription animal drugs" and, by that fact alone, they fall within Section 201.105 coverage. . . . [T]he collateral use of the NAD status of these drugs as proof that they are unsafe under Section 201.105 . . . relies on two possibly invalid assumptions: first, that the Secretary actually considered whether or not the drugs required the cautionary label and, if so, second, that the decision was based on a finding that the drugs were in fact unsafe without the label.

Sixth Circuit Opinion, App. at A18, A20 (footnote omitted). The FDA admits in its brief before this Court that veterinary drug distributors such as IBA have no opportunity to participate in the proceeding in which the "decision" to apply a prescription label is made. See Opposing Brief, pp. 3-4, n.2 where the Government admits that "the FDA's decision whether to approve a drug is not a public proceeding" that "the pendency of an NADA is confidential," and "only the sponsor can appeal the decision." Nor does the Government deny that the prescription label is voluntarily offered by the manufacturer of the veterinary drug to speed up the approval process. By so doing, the manufacturer avoids the necessity of providing expert testimony and clinical testing to support a claim that the drug contains adequate directions for lay use.

As a result, the party with absolutely no incentive to market a veterinary drug without the prescription label (the manufacturer) is the only party with a right to assert that the drug contains adequate directions for

lay use. On the other hand, a distributor or dealer who sells biologically equivalent veterinary drugs, one of which bears the manufacturer's voluntary prescription label and another which does not,¹ is precluded from defending a misbranding charge by proving that the prescription label is unnecessary because the drug contains adequate directions for lay use.

Such reasoning is wholly contrary to the law of this Court that due process cannot be trampled by the doctrine of collateral estoppel, as expressed in *United States v. Utah Construction & Mining Co.*, 384 U.S. 394, 422 (1966) and *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 319, 329 (1971).

At pages 10 and 11 of its Opposing Brief, the Government suggests a parade of horrors which would result if this Court were to enforce IBA's fundamental rights to defend against misbranding charges. These are illusory. First, veterinary drug distributors could not "at any time obtain de novo review in district court of FDA's determination regarding the prescription status of a drug . . .". Opposing Brief, p. 10. The distributor simply would be permitted to raise its traditional statutory defense, adequate directions for lay use, in a misbranding proceeding—an issue not addressed by the FDA in any factfinding proceeding. Second, sponsors of a New Animal Drug could not obtain de novo review. *Id.*, p. 11. By voluntarily offering to put the prescription label on the veterinary drug

1. For example, one of the veterinary drugs which the FDA alleged in its complaint to be a toxic "prescription" drug, and which was included in the injunction issued by the trial court, was later removed pursuant to stipulation by the Government that the same drug was also sold over-the-counter ("OTC"). Nevertheless, IBA was not permitted to defend this action on the grounds that other of the allegedly prescription drugs were sold OTC.

during the application process, the sponsor would have waived, or be estopped from raising, that claim. Finally, the "considerable uncertainty" which would allegedly be engendered by different federal courts considering individual defenses is neither greater nor worse than the uncertainty which inherently results when federal district courts fulfill their duty to enforce federal statutes.

Finally, the United States ignores the fact that two of the enjoined drugs are not NADA's, and thus did not even go through the truncated application process which the Government claims to be binding in this case. Judge Jones noted these discrepancies in his dissent, App. at A21-23.

In sum, the FDA has attempted, with a most dubious interpretation of its power to promulgate regulations governing veterinary drugs which do not require adequate directions for lay use, to create a "prescription" category for veterinary drugs. Historically, however, the agency has recognized that its regulation cannot go so far as to eradicate the statute's explicit defense that a veterinary drug which contains adequate directions for lay use is not misbranded. In this case, the FDA has assumed authority beyond that of the legislature or judiciary, in violation of fundamental due process limits on the use of collateral estoppel and contrary to the clear language of the statute. This Court should not allow summary injunctions against veterinary drug wholesalers, distributors, and dealers based on the collateral effect of a closed administrative proceeding in which no fact findings are made and in which the only party who can appeal the prescription label requirement not only has no incentive to appeal, but is encouraged to place a restrictive label on the drug voluntarily.

CONCLUSION

The Petition for Writ of Certiorari should be granted, the summary judgment and injunction vacated, and the case remanded to the trial court for trial on the defenses raised by IBA.

Respectfully submitted,

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